UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 16, 2022

INTELLIA THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37766**	**36-4785571**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

40 Erie Street, Suite 130 **Cambridge, Massachusetts** **(Address of Principal Executive Offices)**	**02139** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (857) 285-6200

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (Par Value $0.0001)	**NTLA**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 16, 2022, Intellia Therapeutics, Inc. (the "Company" or "Intellia") issued a press release titled "Intellia and Regeneron Announce Initial Data from the Cardiomyopathy Arm of Ongoing Phase 1 Study of NTLA-2001, an Investigational CRISPR Therapy for the Treatment of Transthyretin (ATTR) Amyloidosis". A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On September 16, 2022, Intellia issued a press release titled "Intellia Therapeutics Announces Positive Interim Clinical Data for its Second Systemically Delivered Investigational CRISPR Candidate, NTLA-2002 for the Treatment of Hereditary Angioedema (HAE)." A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 hereto, are being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

Interim Clinical Data of NTLA-2001

On September 16, 2022, the Company announced, together with Regeneron Pharmaceuticals, Inc. ("Regeneron"), additional positive interim results from an ongoing Phase 1 clinical trial of NTLA-2001. The interim data include 12 adult patients with ATTR amyloidosis with cardiomyopathy ("ATTR-CM") with New York Heart Association (NYHA) Class I – III heart failure. Single doses of 0.7 mg/kg and 1.0 mg/kg of NTLA-2001 were administered via intravenous infusion, and the change from baseline in serum transthyretin ("TTR") protein concentration was measured for each patient.

Administration of NTLA-2001 led to rapid and deep reductions in serum TTR by day 28 as follows:

Cohort	Mean (min, max) % serum TTR reduction by day 28
0.7 mg/kg, NYHA Class I/II (n=3)*	92% (91%, 95%)
0.7 mg/kg, NYHA Class III (n=6)*	94% (91%, 97%)
1.0 mg/kg, NYHA Class I/II (n=3)	92% (90%, 95%)

* Mean (min, max) % serum TTR reduction by day 28 for 0.7 mg/kg cohort (n=9) was 93% (91%, 97%).

These profound reductions in serum TTR were sustained throughout the observation period, with patient follow-up ranging from two to six months as of the data cut-off date of July 1, 2022. The Company believes these data support NTLA-2001's potential as a one-time treatment to permanently inactivate the *TTR* gene and reduce the disease-causing protein in people with ATTR-CM.

NTLA-2001 is the first CRISPR/Cas9-based therapy candidate to be administered systemically for precision editing of a gene in humans. It is designed to inactivate the *TTR* gene in liver cells to reduce the production of misfolded TTR protein, which accumulates in tissues throughout the body and causes the debilitating and often fatal complications of ATTR amyloidosis.

At both dose levels, NTLA-2001 was generally well tolerated. Two of 12 patients reported transient infusion reactions, which was the only observed treatment-related adverse event. One patient in the 0.7 mg/kg dose NYHA Class III cohort experienced a Grade 3 infusion-related reaction, which resolved without clinical consequence. Per the study protocol, this group was subsequently expanded from three to six patients to further characterize safety at this dose level. No additional patients in the 0.7 mg/kg dose NYHA Class III cohort reported a treatment-related adverse event. No clinically significant liver findings were observed at either dose level.

The Phase 1 study, run by the Company as the program's development and commercialization lead as part of a multi-target collaboration with Regeneron, is evaluating NTLA-2001 in patients with either ATTR-CM or hereditary ATTR amyloidosis with polyneuropathy ("ATTRv-PN"). A protocol amendment has been submitted to evaluate a fixed dose corresponding to 0.7 mg/kg in the dose-expansion portion, with enrollment across both arms expected to be completed by the end of 2022, subject to regulatory feedback.

Interim Clinical Data of NTLA-2002

On September 16, 2022, at the 2022 Bradykinin Symposium, the Company presented positive interim results from an ongoing Phase 1/2 clinical study of our second *in vivo* genome editing candidate, NTLA-2002, which is being developed as a single-dose treatment for hereditary angioedema ("HAE"). The interim data presented are from the initial six adult patients with HAE treated in the ongoing dose-escalation study with a data cut-off date of July 27, 2022. Single doses of 25 mg (n=3) and 75 mg (n=3) of NTLA-2002 were administered via intravenous infusion, and changes from baseline values of plasma kallikrein protein were measured for each patient. Administration of NTLA-2002 led to dose-dependent reductions in plasma kallikrein and achieved maximal reductions by week eight, with mean reductions of 65% and 92% in the 25 mg and 75 mg dose cohorts, respectively. Furthermore, these reductions have been sustained through at least 16 weeks in the 25 mg cohort and 8 weeks in the 75 mg cohort for which complete cohort biomarker data were available.

In addition to plasma kallikrein levels, HAE attack rates are also being measured in the study, with the first analysis occurring at the end of the pre-specified 16-week primary observation period. To date, all three patients in the 25 mg dose cohort have reached the end of this initial observation period. Patients in this group had a baseline HAE attack rate ranging from 1.1 to 7.2 attacks per month, as confirmed by the investigator. Treatment with a single dose of 25 mg of NTLA-2002 resulted in a mean reduction in HAE attacks of 91% throughout the 16-week observation period. Additionally, two of the three patients have not had a single HAE attack since treatment, and all three patients have been attack free since week 10 (follow-up through weeks 24 - 32). Patients in the 75 mg cohort have not completed the primary 16-week observation period, and attack rate data for this cohort will be presented at the American College of Allergy, Asthma & Immunology Annual Scientific Meeting, November 10 –14 in Louisville, Kentucky.

Prophylaxis medications are permitted in the Phase 1 part of the study. Two of the three patients in the 25 mg cohort were actively receiving prophylaxis therapy prior to administration of NTLA-2002. For these two patients, the study protocol permitted investigators to withdraw the patient's prophylaxis therapy after completion of the 16-week primary observation period. This treatment approach was implemented for the two applicable patients in this cohort, and neither patient has had an HAE attack since discontinuing their prophylaxis therapy through the latest follow-up.

At both dose levels, NTLA-2002 was generally well tolerated, and the majority of adverse events were mild in severity. The most frequent adverse events were infusion-related reactions, which were mostly Grade 1 and resolved within one day. There have been no dose-limiting toxicities, no serious adverse events and no adverse events of Grade 3 or higher observed to date. No clinically significant laboratory abnormalities were observed, including any significant elevation in liver enzymes.

Based on the interim data presented in September 2022, the Company selected a third dose of 50 mg to be evaluated in the ongoing dose-escalation portion of the Phase 1/2 study. Dosing at this level has recently been completed and the Company expects to select up to two doses to further evaluate in the Phase 2, placebo-controlled dose expansion portion of the study, which is expected to begin in the first half of 2023. The Company anticipates expanding country and site participation, including U.S. clinical sites, as part of the Phase 2 study.

NTLA-2002 is designed to inactivate the *KLKB1* gene in liver cells. By targeting the *KLKB1* gene, NTLA-2002 reduces the production of kallikrein protein, whose uncontrolled activity is responsible for the overproduction of bradykinin, which leads to the recurring, debilitating and potentially fatal swelling attacks that occur in people living with HAE.

Forward Looking Statements

This Current Report on Form 8-K and certain of the materials furnished or filed herewith contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding Intellia's beliefs and expectations regarding its: ability to enroll and dose the necessary subjects in the clinical studies for NTLA-2001 for the treatment of ATTR amyloidosis and NTLA-2002 for the treatment of HAE; provide timing on data readouts from the clinical studies, and successfully secure additional clinical studies authorizations, such as investigational new drug applications ("IND") and CTA, in other countries; ability to evaluate NTLA-2001 in a broader ATTR amyloidosis population; expectation that clinical results will support NTLA-2001's safety and activity profile; belief that NTLA-2001 can be approved as a single-dose therapy or that it can halt and potentially reverse ATTR amyloidosis progression; ability to evaluate NTLA-2002 in a broader HAE population advancement, expansion and acceleration of our CRISPR/Cas9 technology and *in vivo* pipeline to develop breakthrough genome editing treatments for people living with severe diseases; ability to optimize the impact of our collaborations on our development programs, including but not limited to our collaboration with Regeneron; and statements regarding the timing of regulatory filings and clinical trial execution, including enrollment and dosing of patients, and regarding our development programs.

Any forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements, including, without limitation, uncertainties related to market conditions as well as on the timing and anticipated results of its clinical trials, strategy and future operations; the delay of any current or planned clinical trials or the development of the Company's drug candidates; the risk that the results of its clinical trials may not be predictive of future results in connection with future clinical trials; the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of its planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the U.S Securities and Exchange Commission ("SEC"), as well as discussions of potential risks, uncertainties, and other important factors in Intellia's other filings with the SEC, including those contained or incorporated by reference. Any forward-looking statements represent Intellia's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Intellia explicitly disclaims any obligation to update any forward-looking statements, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated September 16, 2022
99.2	Press release, dated September 16, 2022
104	104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 16, 2022

Intellia Therapeutics, Inc.

By: /s/ John M. Leonard
Name: John M. Leonard
Title: Chief Executive Officer and President

PRESS RELEASE

Intellia and Regeneron Announce Initial Data from the Cardiomyopathy Arm of Ongoing Phase 1 Study of NTLA-2001, an Investigational CRISPR Therapy for the Treatment of Transthyretin (ATTR) Amyloidosis

- *Interim data from the cardiomyopathy arm of the Phase 1 study of NTLA-2001 showed deep and sustained mean serum transthyretin (TTR) reductions of 93% and 92% at 0.7 mg/kg and 1.0 mg/kg doses, respectively, at day 28*
- *NTLA-2001 was generally well-tolerated at both dose levels*
- *Intellia to discuss data at investor event today, Friday, September 16, at 8:00 a.m. ET*

CAMBRIDGE, Mass. and TARRYTOWN, N.Y., Sept. 16, 2022 – Intellia Therapeutics, Inc. (NASDAQ:NTLA) and Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced positive interim results from an ongoing Phase 1 clinical trial of NTLA-2001, an investigational, *in vivo* CRISPR/Cas9 genome editing therapy in development as a single-dose treatment for transthyretin (ATTR) amyloidosis. The interim data include 12 adult patients with ATTR amyloidosis with cardiomyopathy (ATTR-CM) with New York Heart Association (NYHA) Class I – III heart failure. Single doses of 0.7 mg/kg and 1.0 mg/kg of NTLA-2001 were administered via intravenous infusion, and the change from baseline in serum transthyretin (TTR) protein concentration was measured for each patient.

Administration of NTLA-2001 led to rapid and deep reductions in serum TTR by day 28 as follows:

Cohort	Mean (min, max) % serum TTR reduction by day 28
0.7 mg/kg, NYHA Class I/II (n=3)*	92% (91%, 95%)
0.7 mg/kg, NYHA Class III (n=6)*	94% (91%, 97%)
1.0 mg/kg, NYHA Class I/II (n=3)	92% (90%, 95%)

* *Mean (min, max) % serum TTR reduction by day 28 for 0.7 mg/kg cohort (n=9) was 93% (91%, 97%).*

These profound reductions in serum TTR were sustained throughout the observation period, with patient follow-up ranging from two to six months as of the data cut-off date of July 1, 2022. These data support NTLA-2001's potential as a one-time treatment to permanently inactivate the *TTR* gene and reduce the disease-causing protein in people with ATTR-CM.

“ATTR amyloidosis is a multifaceted disease in need of additional treatment options. These new interim results demonstrate that NTLA-2001 can profoundly reduce serum TTR levels in patients whose condition results in cardiomyopathy,” said Intellia President and Chief Executive Officer John Leonard, M.D. “Together with the previously reported data from the polyneuropathy arm of this landmark study, these results strongly suggest that NTLA-2001 could serve as a single-dose treatment regardless of disease manifestation. At these deep and consistent levels of protein reduction, we believe NTLA-2001 has the potential to halt and even reverse the underlying cause of ATTR amyloidosis. Given the similarly robust TTR reductions observed at the two doses tested, we have selected a fixed dose comparable to the 0.7 mg/kg level for evaluation across both arms in the ongoing dose-expansion portion of the study. We look forward to completing the Phase 1 study as we advance closer to a potential pivotal trial, which we expect will include patients in the U.S.”

“We’re encouraged to see profound and sustained serum TTR reductions in people with cardiomyopathy manifestations of this rare and fatal disease, further bolstering the prospects for a one-time, *in vivo* treatment for multiple ATTR patient groups,” said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. “Intellia and Regeneron are working together diligently to advance this potentially groundbreaking application of CRISPR technology, which could one day be used for many different genetic diseases.”

At both dose levels, NTLA-2001 was generally well tolerated. Two of 12 patients reported transient infusion reactions, which was the only observed treatment-related adverse event. One patient in the 0.7 mg/kg dose NYHA Class III cohort experienced a Grade 3 infusion-related reaction, which resolved without clinical consequence. Per the study protocol, this group was subsequently expanded from three to six patients to further characterize safety at this dose level. No additional patients in the 0.7 mg/kg dose NYHA Class III cohort reported a treatment-related adverse event. No clinically significant liver findings were observed at either dose level.

The Phase 1 study, run by Intellia as the program’s development and commercialization lead as part of a multi-target collaboration with Regeneron, is evaluating NTLA-2001 in patients with either ATTR-CM or hereditary ATTR amyloidosis with polyneuropathy (ATTRv-PN). A protocol amendment has been submitted to evaluate a fixed dose corresponding to 0.7 mg/kg in the dose-expansion portion, with enrollment across both arms expected to be completed by the end of 2022, subject to regulatory feedback.

NTLA-2002 Interim Clinical Results

In a separate press release issued earlier today, Intellia announced positive interim clinical data from an ongoing Phase 1/2 clinical study of NTLA-2002, its second *in vivo* genome editing candidate, for the treatment of hereditary angioedema (HAE). Please visit this link, or the Press Releases section of the company's website at www.intelliatx.com.

Intellia Therapeutics Investor Event and Webcast Information

Intellia will host a live webcast today, Friday, September 16, 2022, at 8:00 a.m. ET, to provide a clinical update from its *in vivo* portfolio, during which the company will review these results from NTLA-2001 alongside interim data from NTLA-2002. To join the webcast, please visit this link, or the Events and Presentations page of the Investors & Media section of the company's website at www.intelliatx.com. A replay of the webcast will be available on Intellia's website for at least 30 days following the call.

About NTLA-2001

Based on Nobel Prize-winning CRISPR/Cas9 technology, NTLA-2001 could potentially be the first single-dose treatment for ATTR amyloidosis. NTLA-2001 is the first investigational CRISPR therapy candidate to be administered systemically, or through a vein, to edit genes inside the human body. Intellia's proprietary non-viral platform deploys lipid nanoparticles to deliver to the liver a two-part genome editing system: guide RNA specific to the disease-causing gene and messenger RNA that encodes the Cas9 enzyme, which carries out the precision editing. Robust preclinical data, showing deep and long-lasting transthyretin (TTR) reduction following *in vivo* inactivation of the target gene, supports NTLA-2001's potential as a single-administration therapeutic. Intellia leads development and commercialization of NTLA-2001 as part of a multi-target discovery, development and commercialization collaboration with Regeneron. The global Phase 1 trial is an open-label, multi-center, two-part study of NTLA-2001 in adults with hereditary transthyretin amyloidosis with polyneuropathy (ATTRv-PN) or transthyretin amyloidosis with cardiomyopathy (ATTR-CM).
Visit clinicaltrials.gov (NCT04601051) for more details.

About Transthyretin (ATTR) Amyloidosis

Transthyretin amyloidosis, or ATTR amyloidosis, is a rare, progressive and fatal disease. Hereditary ATTR (ATTRv) amyloidosis occurs when a person is born with mutations in the *TTR* gene, which causes the liver to produce structurally abnormal transthyretin (TTR) protein with a propensity to misfold. These damaged proteins build up as amyloid in the body, causing serious complications in multiple tissues, including the heart, nerves and digestive system. ATTRv amyloidosis predominantly manifests as polyneuropathy (ATTRv-PN), which can lead to nerve damage, or cardiomyopathy (ATTRv-CM), which can lead to heart failure. Some individuals without the genetic mutation produce non-mutated, or wild-type TTR proteins that become unstable over time, misfolding and aggregating in disease-causing amyloid deposits. This condition, called wild-type ATTR (ATTRwt) amyloidosis, primarily affects the heart. There are an estimated 50,000 people worldwide living with ATTRv amyloidosis and between 200,000 and 500,000 people with ATTRwt amyloidosis.

About Intellia Therapeutics

Intellia Therapeutics, a leading clinical-stage genome editing company, is developing novel, potentially curative therapeutics leveraging CRISPR-based technologies. To fully realize the transformative potential of CRISPR-based technologies, Intellia is pursuing two primary approaches. The company's *in vivo* programs use intravenously administered CRISPR as the therapy, in which proprietary delivery technology enables highly precise editing of disease-causing genes directly within specific target tissues. Intellia's *ex vivo* programs use CRISPR to create the therapy by using engineered human cells to treat cancer and autoimmune diseases. Intellia's deep scientific, technical and clinical development experience, along with its robust intellectual property portfolio, have enabled the company to take a leadership role in harnessing the full potential of genome editing to create new classes of genetic medicine. Learn more at intelliatx.com. Follow us on Twitter @intelliatx.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Intellia Forward-Looking Statements

This press release contains "forward-looking statements" of Intellia Therapeutics, Inc. ("Intellia" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Intellia's beliefs and expectations regarding: its ability to conduct and complete clinical studies for NTLA-2001 for the treatment of transtherytin amyloidosis (ATTR); its ability to generate data to demonstrate NTLA-2001 as a potential single-dose treatment for ATTR; the belief that NTLA-2001 can halt and potentially even reverse the underlying cause of ATTR; its ability to develop its modular platform and full-spectrum approach to advance its complex genome

editing capabilities, including to apply its proprietary CRISPR/Cas9 technology platform to additional product candidates; the advancement and expansion of its CRISPR/Cas9 technology to develop human therapeutic products; its ability to maintain and expand its related intellectual property portfolio, and avoid or acquire rights to valid intellectual property of third parties; its ability to demonstrate its platform's modularity and replicate or apply results achieved in preclinical studies, including those in its NTLA-2001 program, in any future studies, including human clinical trials; its ability to develop other in vivo or ex vivo cell therapeutics of all types, and NTLA-2001 in particular, using CRISPR/Cas9 technology; and the timing of regulatory filings and clinical trial execution, including enrollment and dosing of patients.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to the successful enrollment of patients in the Phase 1 study for NTLA-2001 for the treatment of ATTRv-PN or ATTR-CM; risks related to Intellia's ability to protect and maintain its intellectual property position; risks related to the authorization, initiation and conduct of studies and other development requirements, including manufacturing, for its in vivo and ex vivo product candidates, including NTLA-2001; the risk that any one or more of Intellia's product candidates, including NTLA-2001, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies, including for NTLA-2001, will not be predictive of future results in connection with future studies; and the risk that Intellia's will not be able to demonstrate its platform's modularity and replicate or apply results achieved in preclinical studies to develop additional product candidates, including to apply its proprietary CRISPR/Cas9 technology platform successfully to additional product candidates. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Intellia's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K and quarterly report of Form 10-Q, as well as discussions of potential risks, uncertainties and other important factors in Intellia's other filings with the Securities and Exchange Commission (SEC). All information in this press release is as of the date of the release, and Intellia undertakes no duty to update this information unless required by law.

Regeneron Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, such as NTLA-2001 (a product candidate being developed for transthyretin (ATTR) amyloidosis under a multi-target discovery, development, and commercialization collaboration between Regeneron and Intellia Therapeutics, Inc.); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (including the Phase 1 clinical study evaluating NTLA-2001 discussed in this press release) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the potential of the CRISPR/Cas9

genome editing technology discussed in this press release for in vivo therapeutic development; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as NTLA-2001); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates (such as NTLA-2001) and new indications for Regeneron's Products; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron and/or its collaborators to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates (such as NTLA-2001) in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's collaboration with Intellia Therapeutics, Inc. discussed in this press release, to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV® (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2021 and its Form 10-Q for the quarterly period ended June 30, 2022. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (https://newsroom.regeneron.com/) and its Twitter feed (https://twitter.com/regeneron).

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# # #

PRESS RELEASE

Intellia Therapeutics Announces Positive Interim Clinical Data for its Second Systemically Delivered Investigational CRISPR Candidate, NTLA-2002 for the Treatment of Hereditary Angioedema (HAE)

- *Positive interim clinical data further validate the modularity of Intellia's industry-leading genome editing platform and its potential to target a multitude of genetic diseases*
- *A single dose of NTLA-2002 led to a 65% and 92% mean plasma kallikrein reduction at 25 mg and 75 mg doses, respectively, at week eight*
- *HAE attacks were reduced by 91% in the 25 mg dose cohort through week 16; two of three patients remain attack free since treatment with third patient attack free since week 10 through latest follow-up*
- *NTLA-2002 was generally well-tolerated at both dose levels*
- *Intellia plans to initiate the Phase 2 dose-expansion portion of the study in 1H 2023*
- *Intellia to host investor event today, Friday, September 16, at 8:00 a.m. ET*

CAMBRIDGE, Mass., Sept. 16, 2022 (GLOBE NEWSWIRE) — Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage genome editing company focused on developing potentially curative therapeutics leveraging CRISPR-based technologies, today announced positive interim results from an ongoing Phase 1/2 clinical study of NTLA-2002, its second *in vivo* genome editing candidate. NTLA-2002 is a systemically administered CRISPR candidate being developed for hereditary angioedema (HAE) and is designed to knock out the *KLKB1* gene in liver cells, thereby reducing the production of kallikrein protein. Uncontrolled activity of kallikrein is responsible for the overproduction of bradykinin, which leads to the recurring, debilitating and potentially fatal swelling attacks that occur in people living with HAE. The interim data were shared today in an oral presentation at the 2022 Bradykinin Symposium held in Berlin, Germany.

The data presented are from the initial six adult patients with HAE in the ongoing dose-escalation study with a data cut-off date of July 27, 2022. Single doses of 25 mg (n=3) and 75 mg (n=3) of NTLA-2002 were administered via intravenous infusion, and changes from baseline values of plasma kallikrein protein were measured for each patient. Administration of NTLA-2002 led to dose-dependent reductions in plasma kallikrein and achieved maximal reductions by week eight, with mean reductions of 65% and 92% in the 25 mg and 75 mg dose cohorts, respectively. Furthermore, these reductions were sustained through at least 16 weeks in the 25 mg cohort and eight weeks in the 75 mg cohort for which complete cohort biomarker data were available.

In addition to plasma kallikrein levels, HAE attack rates are also being measured in the study, with the first analysis occurring at the end of the pre-specified 16-week primary observation period. To date, all three patients in the 25 mg dose cohort have reached the end of this initial observation period. Patients in this group had a baseline HAE attack rate ranging from 1.1 to 7.2 attacks per month, as confirmed by the investigator. Treatment with a single dose of 25 mg of NTLA-2002 resulted in a mean reduction in HAE attacks of 91% throughout the 16-week observation period. Additionally, two of the three patients have not had a single HAE attack since treatment, and all three patients have been attack free since week 10 (follow-up through weeks 24—32). Patients in the 75 mg cohort have not completed the primary 16-week observation period. Attack-rate data for this cohort will be presented at the American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting, November 10 – 14 in Louisville, Kentucky.

Prophylaxis medications are permitted in the Phase 1 part of the study. Two of the three patients in the 25 mg cohort were actively receiving prophylaxis therapy prior to administration of NTLA-2002. For these two patients, the study protocol permitted investigators to withdraw the patient's prophylaxis therapy after completion of the 16-week primary observation period. This treatment approach was implemented for the two applicable patients in this cohort, and neither patient has had an HAE attack since discontinuing their prophylaxis therapy through the latest follow-up.

"These initial data represent a significant milestone for both Intellia and people around the world suffering from genetic diseases, such as HAE," said Intellia President and Chief Executive Officer John Leonard, M.D. "We are strongly encouraged by the greater than 90% reduction in HAE attacks observed in the 25 mg dose cohort, as these interim results support our belief that a single dose of NTLA-2002 has the potential to permanently prevent the debilitating swelling attacks associated with HAE. Additionally, today's announcement continues to validate our genome editing approach and the modular platform we have built. This is now the second time in history clinical data have been generated suggesting we can precisely edit target cells within the human body to potentially treat genetic diseases with a single, systemic administration of a CRISPR-based therapy. We plan to move as quickly and judiciously as possible on behalf of people living with HAE and a number of additional genetic diseases in the months and years ahead."

At both dose levels, NTLA-2002 was generally well-tolerated, and the majority of adverse events were mild in severity. The most frequent adverse events were infusion-related reactions, which were mostly Grade 1 and resolved within one day. There have been no dose-limiting toxicities, no serious adverse events and no adverse events of Grade 3 or higher observed to date. No clinically significant laboratory abnormalities were observed, including any significant elevation in liver enzymes.

“Many people living with HAE continue to experience breakthrough attacks despite currently available treatments and often find the burden of untreated attacks, frequent infusions or injections to be tremendously disruptive to their lives,” said Hilary Longhurst, M.D., Ph.D., Faculty of Medical and Health Sciences, University of Auckland, New Zealand, and the trial’s principal investigator in New Zealand. “These early data support NTLA-2002 as a potential one-time treatment capable of producing profound reductions in HAE attacks. While the clinical data are still emerging, I am highly optimistic that NTLA-2002 could become a new treatment option for the HAE community.”

Based on the interim data presented today, Intellia selected a third dose of 50 mg to be evaluated in the ongoing dose-escalation portion of the Phase 1/2 study. Dosing at this level has recently completed, and Intellia expects to select up to two doses to further evaluate in the Phase 2, placebo-controlled, dose-expansion portion of the study, which is expected to begin in the first half of 2023. Intellia anticipates expanding country and site participation, including U.S. clinical sites, as part of the Phase 2 study.

Intellia Therapeutics Investor Event and Webcast Information

Intellia will host a live webcast today, Friday, September 16, 2022, at 8:00 a.m. ET, to provide a clinical update from its *in vivo* portfolio, during which the company will review the presented clinical data at the 2022 Bradykinin Symposium alongside interim results from NTLA-2001. To join the webcast, please visit this link, or the Events and Presentations page of the Investors & Media section of the company’s website at www.intelliatx.com. A replay of the webcast will be available on Intellia’s website for at least 30 days following the call.

About the NTLA-2002 Clinical Program

Intellia’s multi-national Phase 1/2 study is evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of NTLA-2002 in adults with Type I or Type II hereditary angioedema (HAE). This includes the measurement of plasma kallikrein protein levels and activity as determined by HAE attack rate measures. The Phase 1 portion of the study is an open-label, single-ascending dose design used to identify up to two dose levels of NTLA-2002 that will be further evaluated in the randomized, placebo-controlled Phase 2 portion of the study. This Phase 1/2 study will identify the dose of NTLA-2002 for use in future studies. Visit clinicaltrials.gov (NCT05120830) for more details.

About NTLA-2002

Based on Nobel Prize-winning CRISPR/Cas9 technology, NTLA-2002 is the first single-dose investigational treatment being explored in clinical trials for the potential to continuously reduce kallikrein activity and prevent attacks in people living with hereditary angioedema (HAE). NTLA-2002 is a wholly owned investigational CRISPR therapeutic candidate designed to inactivate the *kallikrein B1 (KLKB1*) gene, which encodes for prekallikrein, the kallikrein precursor protein. NTLA-2002 is Intellia's second investigational CRISPR therapeutic candidate to be administered systemically, by intravenous infusion, to edit disease-causing genes inside the human body with a single dose of treatment. Intellia's proprietary non-viral platform deploys lipid nanoparticles to deliver to the liver a two-part genome editing system: guide RNA specific to the disease-causing gene and messenger RNA that encodes the Cas9 enzyme, which together carry out the precision editing.

About Hereditary Angioedema

Hereditary angioedema (HAE) is a rare, genetic disorder characterized by severe, recurring and unpredictable inflammatory attacks in various organs and tissues of the body, which can be painful, debilitating and life-threatening. It is estimated that one in 50,000 people are affected by HAE, and current treatment options often include life-long therapies, which may require chronic intravenous (IV) or subcutaneous (SC) administration as often as twice per week, or daily oral administration to ensure constant pathway suppression for disease control. Despite chronic administration, breakthrough attacks still occur. Kallikrein inhibition is a clinically validated strategy for the preventive treatment of HAE attacks.

About Intellia Therapeutics

Intellia Therapeutics, a leading clinical-stage genome editing company, is developing novel, potentially curative therapeutics leveraging CRISPR-based technologies. To fully realize the transformative potential of CRISPR-based technologies, Intellia is pursuing two primary approaches. The company's *in vivo* programs use intravenously administered CRISPR as the therapy, in which proprietary delivery technology enables highly precise editing of disease-causing genes directly within specific target tissues. Intellia's *ex vivo* programs use CRISPR to create the therapy by using engineered human cells to treat cancer and autoimmune diseases. Intellia's deep scientific, technical and clinical development experience, along with its robust intellectual property portfolio, have enabled the company to take a leadership role in harnessing the full potential of genome editing to create new classes of genetic medicine. Learn more at intelliatx.com. Follow us on Twitter @intelliatx.

Forward-Looking Statements

This press release contains "forward-looking statements" of Intellia Therapeutics, Inc. ("Intellia" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Intellia's beliefs and expectations regarding: its ability to conduct and complete clinical studies for NTLA-2002 for the treatment of hereditary angioedema (HAE); its ability to generate data to demonstrate NTLA-2002 as a potential single-dose treatment for HAE, including safety, kallikrein reduction and attack rate data including permanently preventing debilitating swelling attacks; its ability to develop its modular platform and full-spectrum approach to advance its complex genome editing capabilities, including to apply its proprietary cell engineering platform to additional product candidates; the advancement and expansion of its CRISPR/Cas9 technology to develop

human therapeutic products; its ability to maintain and expand its related intellectual property portfolio, and avoid or acquire rights to valid intellectual property of third parties; its ability to demonstrate its platform's modularity and replicate or apply results achieved in preclinical studies, including those in its NTLA-2002 program, in any future studies, including human clinical trials; its ability to develop other in vivo or ex vivo cell therapeutics of all types, and NTLA-2002 in particular, using CRISPR/Cas9 technology; and the timing of regulatory filings and clinical trial execution, including enrollment and dosing of patients.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to the successful enrollment of patients in the Phase 1/2 study for NTLA-2002 for the treatment of HAE; risks related to Intellia's ability to protect and maintain its intellectual property position; risks related to the authorization, initiation and conduct of studies and other development requirements, including manufacturing, for its in vivo and ex vivo product candidates, including NTLA-2002; the risk that any one or more of Intellia's product candidates, including NTLA-2002, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies, including for NTLA-2002, will not be predictive of future results in connection with future studies; and the risk that Intellia's will not be able to demonstrate its platform's modularity and replicate or apply results achieved in preclinical studies to develop additional product candidates, including to apply its proprietary CRISPR/Cas9 technology platform successfully to additional product candidates. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Intellia's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K and quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties and other important factors in Intellia's other filings with the Securities and Exchange Commission (SEC). All information in this press release is as of the date of the release, and Intellia undertakes no duty to update this information unless required by law.

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