Asterias Provides Top Line 12 Month Data Update for its OPC1 Phase 1/2a Clinical Trial in Severe Spinal Cord Injury

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FREMONT, Calif., Jan. 24, 2019 (GLOBE NEWSWIRE) -- Asterias Biotherapeutics, Inc. (NYSE American: AST), a biotechnology company dedicated to developing cell-based therapeutics to treat neurological conditions associated with demyelination and cellular immunotherapies to treat cancer, today provided top-line 12 month data from the Company's Phase 1/2a SCiStar study designed to evaluate the safety and potential efficacy of OPC1 in the treatment of severe cervical spinal cord injury (SCI). All 25 subjects from the SCiStar study have now completed 12-months of follow-up as part of the study's protocol. The Company also held a Type B meeting with the Food and Drug Administration (FDA) late last year where FDA agreed with the Company's plan to initiate a randomized, controlled Phase 2 study to further evaluate the safety and efficacy of OPC1.

"We believe the primary goal of SCiStar, which was to observe the safety of OPC1 in cervical spinal cord injury patients and to accumulate data related to important factors for the design of later-stage trials, such as optimal dosing levels, timing of OPC1 injection after SCI, the immunosuppression regimen, engraftment of the cells, and rates of motor recovery observed among different study subpopulations, have been successfully achieved," commented Ed Wirth, Chief Medical Officer. "We have also reached preliminary agreement with FDA on the next steps for the clinical development of OPC1, including the eligibility criteria, dose level, and proposed study design for the next clinical trial. We expect to provide an update on the OPC1 program later this year after the merger with BioTime, Inc. has closed."

Below are a summary of key findings at 12 months for the SCiStar study subjects:

- **Positive Safety Profile** –MRI scans at 12 months post-injection of OPC1 has shown no evidence of adverse changes in any of the 25 SCiStar study subjects treated with OPC1. Asterias has dosed a total of 30 subjects including the five subjects from a previous Phase 1 safety trial in thoracic spinal cord injury who have been followed for as long as eight years. To date, there have been no unexpected serious adverse events (SAEs) related to the OPC1 cells.

- **Cell Engraftment** – All three SCiStar subjects in Cohort 1 and 95% (21/22) of SCiStar subjects in Cohorts 2-5 have magnetic resonance imaging (MRI) scans at 12 months consistent with the formation of a tissue matrix at the injury site, which is encouraging evidence that OPC1 cells have engrafted at the injury site and helped to prevent cavitation. The MRI results provide supportive evidence that OPC1 cells have durably engrafted at the injury site and helped to prevent cavitation. Cavitation is a destructive process that occurs within the spinal cord following spinal cord injuries, and typically results in permanent loss of motor and sensory function. Additionally, a patient with cavitation can develop a condition known as syringomyelia, which results in additional neurological and functional damage to the patient and can result in chronic pain.

- **Improved Motor Function** – At 12 months, 95% (21/22) of SCiStar study subjects who were administered either 10 million or 20 million cells of OPC1 (Cohorts 2-5) recovered at least one motor level on at least one side. At 12 months, 32% (7/22) of these subjects recovered two or more motor levels on at least one side. At 12 months, the average improvement in upper extremity motor score as measured by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale for Cohort 2-5 subjects was 8.9 points. No subjects saw decreased motor function following administration of OPC1 and subjects consistently retained the motor function recovery seen through 6 months or saw further motor function recovery from 6 to 12 months.

- **Results Excluding Certain SCiStar Study Subjects**– Excluding those SCiStar subjects in Cohorts 2-5 that would either (i) not meet the eligibility criteria the Company proposed to FDA during its recent Type B meeting to discuss the next study for OPC1 or (ii) receive a modified post-surgical procedure to reduce potential cord compression issues, at 12 months 100% (17/17) of these SCiStar study subjects recovered at least one motor level on at least one side, 41% (7/17) of these subjects recovered two or more motor levels on at least one side, and the average improvement in upper extremity motor score as measured by the ISNCSCI scale for these subjects was 10.2 points.

OPC1 Therapeutic Platform

OPC1, an oligodendrocyte progenitor cell population derived from human embryonic stem cells, has been shown in preclinical testing in animals and in vitro to have three potentially reparative functions that address the complex pathologies observed in demyelination disorders, such as spinal cord injury and multiple neurodegenerative diseases, including multiple sclerosis and white matter stroke. These potential reparative functions of OPC1 include the production of neurotrophic factors, the stimulation of vascularization, and the induction of remyelination of denuded axons, all of which are critical for survival and regrowth of—and conduction of nerve impulses through—axons at the injury site.

Each year in the United States, more than 17,000 people suffer a severe, debilitating spinal cord injury. As of 2016, the National Spinal Cord Injury Statistical Center reported that approximately 4,500 of these new spinal cord injuries annually in the U. S. are AIS-A, AIS-B, or AIS-C patients with C-4

to C-7 spinal cord injuries (https://www.nscisc.uab.edu/). These injuries can be devastating to quality of life and ability to function independently. Lifetime healthcare costs for these patients can often approach $5 million. Improvements in arm, hand, and finger functional capabilities in these patients can result in meaningfully lower healthcare costs, significant improvements in quality of life, greater ability to engage in activities of daily living, and increased independence.

About Asterias Biotherapeutics

Asterias Biotherapeutics, Inc. is a biotechnology company dedicated to developing cell-based therapeutics to treat neurological conditions associated with demyelination and cellular immunotherapies to treat cancer. Asterias is presently focused on advancing three clinical-stage programs which have the potential to address areas of very high unmet medical need in the fields of neurology and oncology. OPC1 (oligodendrocyte progenitor cells) is currently in a Phase 1/2a dose escalation clinical trial in spinal cord injury. VAC2 (antigen-presenting allogeneic dendritic cells) is an allogeneic cancer immunotherapy. The company's research partner, Cancer Research UK, has commenced a first-in-human clinical trial of VAC2 in non-small cell lung cancer. VAC1 (antigen-presenting autologous dendritic cells) is an autologous cancer immunotherapy with promising efficacy and safety data from an earlier Phase 2 study in Acute Myeloid Leukemia (AML). Asterias is also sponsoring pre-clinical work in two conditions with a demyelinating component: Multiple Sclerosis and White Matter Stroke, and is evaluating other cancer indications where its immunotherapy platform could provide therapeutic benefit. Additional information about Asterias can be found at www.asteriasbiotherapeutics.com.

About OPC1

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About the SCiStar Trial

The SCiStar trial is an open-label, single-arm trial testing three sequential escalating doses of OPC1 administered at up to 20 million OPC1 cells in 25 subjects with subacute motor complete (AIS-A or AIS-B) cervical (C-4 to C-7) SCI. These individuals have essentially lost all movement below their injury site and experience severe paralysis of the upper and lower limbs. AIS-A subjects have lost all motor and sensory function below their injury site, while AIS-B subjects have lost all motor function but may have retained some minimal sensory function below their injury site. OPC1 is administered 21 to 42 days post-injury. Subjects will be followed by neurological exams and imaging procedures to assess the safety and activity of the product.

The SCiStar study consists of five cohorts:

Cohort	Injury Type; OPC1 Dose	# of Subjects
Cohort 1	AIS-A; 2M OPC1 cells (low dose for initial safety evaluation)	3
Cohort 2	AIS-A; 10M OPC1 cells	6
Cohort 3	AIS-A; 20M OPC1 cells*	6
Cohort 4	AIS-B; 10M OPC1 cells	6
Cohort 5	AIS-B; 20M OPC1 cells*	4
Total		25

*One subject from Cohort 3 and one subject from Cohort 5 were administered 10 million cells.

Improvements in upper extremity motor function are being measured using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale, widely used to quantify functional status of patients with spinal cord injuries. Both subjects and physicians consistently report that improvements in upper extremity motor function are the most desirable functional improvement target in the quadriplegic population, since even relatively modest changes can potentially have a significant impact on functional independence, quality of life and cost of care. The SCiStar study is monitoring two separate ISNCSCI measurements of upper extremity motor function. The upper extremity motor score (UEMS), is a linear scale used to quantify motor function at each of five upper extremity muscle groups driving arm and hand function; these scores are also used to determine "motor levels", which define the level within the cord above which a subject has normal function. As suggested by existing research, patients with severe spinal cord injuries that show two motor levels of improvement on at least one side may regain the ability to perform daily activities such as feeding, dressing and bathing, which significantly reduces the overall level of daily assistance needed for the patient and associated healthcare costs.

Asterias has received a Strategic Partnerships Award grant from the California Institute for Regenerative Medicine, which provided $14.3 million of non-dilutive funding for the Phase 1/2a clinical trial and other product development activities for OPC1.

Additional information on the Phase 1/2a trial, including trial sites, can be found at www.clinicaltrials.gov, using Identifier NCT02302157, and at the SCiStar Study Website (www.SCiStar-study.com).

FORWARD-LOOKING STATEMENTS

Statements pertaining to future financial and/or operating and/or clinical research results, future growth in research, technology, clinical development, and potential opportunities for Asterias, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Asterias, particularly those mentioned in the cautionary statements found in Asterias' filings with the Securities and Exchange Commission. Asterias disclaims any intent or obligation to update these forward-looking statements. More

information on potential factors that could affect our results is included from time to time in the SEC filings and reports of Asterias, including the risks identified under the sections captioned “Risk Factors” in Asterias’ annual report on Form 10-K filed with the SEC on March 15, 2018, Asterias’ quarterly report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 9, 2018**,** and BioTime’s Registration Statement on Form S-4 containing a Joint Proxy Statement/Prospectus filed with the SEC on January 14, 2019.

IMPORTANT INFORMATION

Additional Information and Where to Find It

This communication is being made in respect of the proposed business combination involving BioTime and Asterias. In connection with the proposed transaction, BioTime and Asterias have filed documents with the SEC, including the filing by BioTime of a Registration Statement on Form S-4 containing a Joint Proxy Statement/Prospectus filed with the SEC on January 14, 2019 and each of BioTime and Asterias plan to file with the SEC other documents regarding the proposed transaction. INVESTORS AND SECURITY HOLDERS OF BIOTIME AND ASTERIAS ARE URGED TO CAREFULLY READ THE JOINT PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS FILED WITH THE SEC BY BIOTIME AND ASTERIAS BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders may obtain free copies of these documents (when they are available) and other documents filed with the SEC at the SEC’s web site at www.sec.gov and by contacting BioTime Investor Relations at (510) 871-4188 or Asterias Investor Relations at (510) 456-3892. Investors and security holders may obtain free copies of the documents filed with the SEC on BioTime’s website at www.biotimeinc.com or Asterias’ website at www.asteriasbiotherapeutics.com or the SEC’s website at www.sec.gov.

Participants in the Solicitation

BioTime, Asterias and their respective directors and executive officers may be deemed participants in the solicitation of proxies with respect to the proposed transaction. Information regarding the interests of these directors and executive officers in the proposed transaction is set forth in the Joint Proxy Statement/Prospectus described above. Additional information regarding the directors and executive officers of BioTime is also included in BioTime’s proxy statement for its 2018 Annual Meeting of Shareholders, which was filed with the SEC on March 29, 2018, and additional information regarding the directors and executive officers of Asterias is also included in Asterias’ proxy statement for its 2018 Annual Meeting of Stockholders, which was filed with the SEC on April 30, 2018.

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