Asterias Biotherapeutics Concludes Recruitment of Initial Safety Cohort of the SCiStar Phase 1/2a Dose-Escalation Clinical Trial of AST-OPC1 for Complete Cervical Spinal Cord Injury

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Safety of the Injection Procedure Confirmed with No Reported Serious Adverse Events

**Menlo Park, Calif. August 31, 2015**– Asterias Biotherapeutics, Inc. (NYSE MKT: AST), a biotechnology company focused on the emerging field of regenerative medicine, today announced that the third patient was successfully dosed at Chicago-based Rush University Medical Center in a Phase 1/2a clinical trial evaluating activity of escalating doses of AST-OPC1 (oligodendrocyte progenitor cells) in newly injured patients with sensory and motor complete cervical spinal cord injury (SCI). This represents the final patient treated at the initial low-dose (2 million cells) safety cohort. The results of the study continue to support a robust safety profile for AST-OPC1, with no serious adverse events observed in any of the three treated patients to date.

The first patient in this cohort was dosed at Shepherd Center in Atlanta and has completed the 2-month post-injection assessment. This patient has progressed from a complete ASIA Impairment Scale (AIS) A injury to an incomplete AIS B injury. The principal investigator at Shepherd Center, Dr. Donald Peck Leslie, said, “This progress in the first patient is very encouraging and is observed in less than 5 percent of our AIS A patients at this stage of their recovery.”

The lead neurosurgeon for the study, Dr. Richard Fessler from Rush University Medical Center, performed the AST-OPC1 injections in the second and third patients. Dr. Fessler stated, “The injection procedure went very smoothly for both patients and there were no complications. Both patients recovered quickly from the injection surgery and were able to resume their rehabilitation programs soon afterward.”

The Company expects to begin enrollment of the second dose cohort following Data Monitoring Committee review of the 30-day post-injection safety data from all three patients. The second cohort will enroll five patients who will receive 10 million AST-OPC1 cells. “The safety data in this first cohort now paves the way for testing the higher doses of AST-OPC1 (10-20 million cells) that we believe correspond most closely to the doses that showed the greatest efficacy in animal studies,” commented Dr. Edward Wirth, Chief Medical Officer of Asterias.

The open-label, single-arm study is being conducted at three centers currently and will include up to twelve centers in the United States. Enrollment in the trial has already begun to accelerate, with 7 weeks elapsed between dosing the first and second patients, and only 3 weeks between dosing the second and third patients.

“We are encouraged by this performance improvement and are confident in meeting our disclosed timelines,” commented Pedro Lichtinger, President and CEO of Asterias. “We expect to provide updates as identified milestones are reached or when major events occur.”

**About the SCi-STAR Trial**

The SCi-STAR trial will test three sequential escalating doses of AST-OPC1 administered at up to 20 million AST-OPC1 cells in 13 patients with sub-acute, C-5 to C-7, neurologically complete cervical SCI. These individuals have essentially lost all sensation and movement below their injury site with severe paralysis of the upper and lower limbs. AST-OPC1 will be administered 14 to 30 days post-injury. Patients will be followed by neurological exams and imaging methods to assess the safety and activity of the product. Additional information on the Phase 1/2a study, including trial sites, can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov/), using Identifier NCT02302157, and at the SCiStar Study Website (www.scistarstudy.com).

Upon achievement of initial safety data from the first two cohorts of this study, Asterias plans to seek concurrence from the U.S. Food and Drug Administration to increase the robustness of the proof of concept in the Phase 1/2a clinical trial by expanding enrollment from 13 patients to up to 40 patients. The Company believes this change will increase the statistical confidence of the safety and efficacy readouts, reduce the risks of the AST-OPC1 program and position the product for potential accelerated regulatory approvals. Asterias has received a Strategic Partnerships Award grant from the California Institute for Regenerative Medicine, which provides $14.3 million of non-dilutive funding for the Phase 1/2a clinical trial and other product development activities for AST-OPC1.

More than 12,000 people sustain a spinal cord injury each year, but there are no FDA-approved therapeutics or devices that could potentially restore some function in individuals who have recently sustained a spinal cord injury.

**About AST-OPC1**

AST-OPC1, an oligodendrocyte progenitor population derived from human embryonic stem cells, has been shown to have three potentially reparative functions that address the complex pathologies observed at the injury site of a spinal cord injury. These activities of AST-OPC1 include production of neurotrophic factors, stimulation of vascularization, and induction of remyelination of denuded axons, all of which are critical for survival, regrowth and conduction of nerve impulses through axons at the injury site. In preclinical animal testing, AST-OPC1 administration led to remyelination of axons, improved hindlimb and forelimb locomotor function, dramatic reductions in injury-related cavitation and significant preservation of myelinated axons traversing the injury site.

In a previous Phase 1 clinical trial, five patients with neurologically complete, thoracic spinal cord injury were administered two million AST-OPC1 cells at the spinal cord injury site 7-14 days post-injury. The subjects received low levels immunosuppression for the next 60 days. Delivery of AST-OPC1 was successful in all five subjects with no serious adverse events associated with the administration of the cells, with AST-OPC1 itself, or the immunosuppressive regimen. No evidence of rejection of AST-OPC1 was observed in detailed immune response monitoring of all subjects. In four of the five subjects, serial MRI scans indicated that reduced spinal cord cavitation may have occurred. Based on the results of this study, Asterias received approval from FDA to progress testing of AST-OPC1 to subjects with complete cervical injuries, which represents the first targeted population for registration trials.

**About Asterias Biotherapeutics**

Asterias Biotherapeutics, Inc. (NYSE MKT: AST) is a leading biotechnology company in the emerging field of regenerative medicine. The Company’s proprietary, industry leading platforms are based on its pluripotent stem cell and dendritic cell immunotherapy technologies. Asterias is focused on developing therapies to treat conditions in several medical areas where there is high unmet medical need and inadequate available therapies. AST-OPC1 (oligodendrocyte progenitor cells) is currently in a Phase 1/2a dose escalation clinical trial in spinal cord injury. AST-VAC1 (antigen-presenting autologous dendritic cells) has demonstrated promise in a Phase 2 study in acute myelogenous leukemia. AST-VAC2 (antigen-presenting allogeneic dendritic cells) represents a second generation, allogeneic approach to dendritic cell vaccines. Additional information about Asterias can be found at www.asteriasbiotherapeutics.com.

**About Rush University Medical Center**

Rush University, with nearly 2,300 students is a health sciences university offering more than 30 unique degree or certificate options in medicine, nursing, allied health and biomedical research. Rush University is comprised of Rush Medical College, the College of Nursing, the College of Health Sciences, and the Graduate College.
Rush University Medical Center is part of Rush, a not-for-profit enterprise that also includes Rush University, Rush Oak Park Hospital and Rush Health. The mission of Rush is to provide the best health care for the individuals and diverse communities we serve through the integration of outstanding patient care, education, research, and community partnerships.
Located one mile west of Chicago’s Loop, the medical center encompasses a 664-bed hospital serving adults and children. The 376-bed Tower building opened in 2012 as part of a major, ten-year campus redevelopment. Rush has more than 9,300 employees and faculty.

**About Shepherd Center**

Shepherd Center, located in Atlanta, Ga., is a private, not-for-profit hospital specializing in medical treatment, research and rehabilitation for people with spinal cord injury, brain injury, multiple sclerosis and chronic pain. Founded in 1975 and now a 152-bed facility, Shepherd Center is ranked by U.S. News & World Report among the top 10 rehabilitation hospitals in the nation. Last year, Shepherd Center had 965 admissions to its inpatient programs and 571 to its day patient programs. In addition, Shepherd Center sees more than 6,600 people annually on an outpatient basis. For more information, visit Shepherd Center online at [www.shepherd.org](http://www.shepherd.org/).

**FORWARD-LOOKING STATEMENTS**

Statements pertaining to future financial and/or operating 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.

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