

Asana BioSciences, LLC

For Immediate Release

Asana BioSciences Announces Acceptance of its Third IND Application in Oncology

Lawrenceville, N.J. October 4, 2016 – Asana BioSciences, LLC, an oncology focused, clinical stage biopharmaceutical company, today announced that the FDA has accepted the IND application for ASN003, a selective RAF/PI3K inhibitor.

“We are extremely pleased with the execution of our strategy to work on clinically validated targets and develop drugs that are clearly differentiated from the competition” said Sandeep Gupta, PhD, Founder, President and Chief Executive Officer at Asana BioSciences. Using a unique, virtual and efficient operating model, Asana is focused on the development of ‘best-in-class’ drugs that are expected to offer significant benefit over the existing standards of care and address unmet medical needs. “To the best of our knowledge, ASN003 is the only molecule in development that selectively targets both RAF and PI3 Kinase pathways. This program represents Asana’s 3rd successful IND in oncology in less than two years and several other lead molecules from our pipeline are positioned to enter clinical development in the near future” stated Dr. Gupta.

The Phase 1, open-label, dose-finding and cohort expansion study will evaluate safety and tolerability of ASN003 as well as preliminary efficacy in patients with advanced solid tumors with RAF or PI3K pathway alterations. The RAS-RAF-MEK and PI3K pathways are two major signaling pathways involved in abnormal cell growth and are frequently mutated in melanoma and other cancers, such as colon and lung cancer. Dual targeting of RAF and PI3K pathways with ASN003 has the potential to overcome and/or delay acquired resistance to selective RAF inhibitors and may thus result in improved activity against cancers driven by both pathways.

Asana’s other lead candidates, ASN001 and ASN002, are in Phase I/II clinical development.

ASN001, a novel and highly selective CYP17 inhibitor that does not require prednisone co-administration, targets metastatic castration resistant prostate cancer. **ASN002** is a novel oral inhibitor of spleen tyrosine kinase (SYK) and Janus kinase (JAK), which is currently in Phase I/II studies in patients with non-Hodgkin’s lymphoma and solid tumors. Evaluation of ASN002 in autoimmune disease indications is also being planned. Both these programs are approaching the end of dose finding phase of the trials and Asana expects to announce initial safety and efficacy results early next year. **ASN004** is an antibody drug conjugate (ADC) targeting 5T4-oncofetal antigen, that selectively and efficiently delivers a cytotoxic agent into tumor cells, resulting in potent, selective anti-proliferative activity and complete tumor regression in multiple tumor models including breast, lung and colon. **ASN007** is a novel ERK inhibitor that shows potent activity against multiple KRAS mutant driven tumor models. These programs will enter clinical development in 2H 2017.

About Asana BioSciences, LLC

Asana BioSciences, LLC, an independent member of the Amneal Alliance of Companies, is a research and development company based in Lawrenceville, NJ, specializing in the discovery and development of new chemical and biological entities. Asana's portfolio consists of multiple early-stage drug discovery and development candidates in a variety of therapeutic areas, including oncology, pain, dermatology and autoimmune diseases.

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