

# Asana BioSciences, LLC

## *For Immediate Release*

### **Asana BioSciences Announces Topical Sodium Channel Blocker ASN008 Achieves Positive Results for the Treatment of Pruritus in Atopic Dermatitis; and Provides Update on JAK/SYK Inhibitor Gusacitinib in Phase 2 Studies for Chronic Hand Eczema and AD**

Lawrenceville, NJ, March 10, 2020 – Asana BioSciences announced today positive topline results from a Phase 1b study evaluating the treatment of pruritus associated with atopic dermatitis (NCT03798561) for its topical sodium channel blocker, ASN008. The Phase 1b double-blind, vehicle-controlled, dose escalation study randomized 25 adult patients with atopic dermatitis and a pruritus score of  $\geq 7$  using the Numerical Rating Scale (NRS) at baseline. Patients were randomized 3:1 receiving either ASN008 gel or vehicle gel applied topically either once or twice daily for 14 days.

The results showed that a single application of ASN008 achieved a clinically meaningful reduction in pruritus of  $\geq 4$  points on the NRS in 2-3 hours, and this effect lasted greater than 8 hours. The anti-pruritic effect of ASN008 was maintained with daily application of ASN008 for two weeks. ASN008 demonstrated low systemic exposure, and safety results show that it was well tolerated with only mild adverse events.

“Pruritus is a condition that affects millions of people worldwide and is associated with a wide range of medical conditions,” said Sandeep Gupta, PhD, Founder and CEO of Asana BioSciences. “We are excited by these clinical data which provide proof-of-concept for ASN008 in the treatment of pruritus associated with atopic dermatitis. The unique mechanism of action of ASN008, which results in selective inhibition of sensory/afferent nerves without affecting motor nerves, positions it as a potentially safe and effective treatment not only for the pruritic conditions but also for pain and other diseases such as cough, interstitial cystitis and overactive bladder that involve overactivity of afferent nerves.”

Asana is also developing an oral Janus kinase (JAK) and Spleen tyrosine kinase (SYK) inhibitor, gusacitinib, for immunology/dermatology indications such as chronic hand eczema and atopic dermatitis.

Chronic Hand Eczema (CHE) is a debilitating condition affecting millions of people worldwide, and currently there are no or very few treatment options for this condition. More importantly, there are no approved treatments for this condition in the U.S. and many other countries. Dr. Robert Bissonnette, dermatologist, President-Elect of International Eczema Council and President of Innovaderm Research said that “Patients with CHE suffer greatly from this disease, which limits the ability to work and perform activities of daily living. JAK/SYK inhibitors, such as gusacitinib, have great potential for the treatment of CHE as they can impact several pathways involved in skin inflammation.” As for treatment of itch in clinical practice, Dr. Bissonnette also

said that “There are numerous causes of chronic itch, and our current treatment armamentarium has limited efficacy in most cases. New treatments to control itch are desperately needed.”

A Phase 2, randomized, double-blind, placebo-controlled, parallel-group study evaluating two doses (40 and 80 mg once daily) of gusacitinib over 32 weeks in moderate-to-severe chronic hand eczema has completed enrollment (NCT03728504). The topline data on the primary endpoint for the change in the hand modified total lesion severity score at week 16 is expected in the second quarter of this year.

Asana has also recently concluded a Phase 2b study (RADIANT) evaluating efficacy and safety of gusacitinib in 244 adult patients with moderate-to-severe atopic dermatitis. The RADIANT study was a randomized, double-blind, placebo-controlled, parallel-group study evaluating three doses (40, 60, and 80 mg once daily) of gusacitinib monotherapy over 12 weeks (NCT03654755).

In the RADIANT trial, gusacitinib achieved the primary endpoint of a statistically significant reduction in the Eczema Area and Severity Index score at the 60 and 80 mg doses compared to placebo at week 12. Gusacitinib also met the key secondary endpoint in the proportion of subjects to achieve an NRS reduction of  $\geq 4$  points with all doses statistically significant from placebo.

Gusacitinib safety results demonstrate that all three doses were well-tolerated with no unexpected safety events. The most common treatment-emergent adverse events observed were headache, nausea, nasopharyngitis, and upper respiratory tract infection. No thromboembolic events, pulmonary embolisms or opportunistic infections were reported in the gusacitinib groups. No malignancies, major adverse cardiovascular events, or deaths were reported in the studies.

### **About ASN008**

ASN008 is a permanently positively charged sodium channel blocker. Sodium channels are required for signaling from sensory neurons, regardless of the stimulus and pruritic conditions arising from the noxious activation and signaling of these sensory (afferent) neurons. ASN008 enters neurons only via activated (open) transient receptor potential vanilloid 1 (TRPV1) channel or the transient receptor potential ankyrin 1 (TRPA1) channel that are selectively expressed on the sensory fibers (C and A $\delta$  fibers). The limited expression of the TRPV1 and TRPA1 channels to the sensory neurons and not the motor neurons means ASN008 is functionally selective, blocking sensory neuron signaling without affecting motor functions. ASN008 provides an opportunity for the treatment of conditions associated with aberrant stimulation of sensory neurons such as chronic pruritus associated with atopic dermatitis and hand eczema, chronic idiopathic pruritus, cough, overactive bladder and painful conditions such as post herpetic neuralgia and interstitial cystitis.

### **About Gusacitinib (ASN002)**

Gusacitinib is a novel oral potent inhibitor of the JAK family (JAK1, JAK2, JAK3 and TYK2) and SYK. Autoimmune, inflammatory and immunological based diseases, including atopic dermatitis, have complex pathogeneses that involve interactions between multiple cytokines, immune cells. Gusacitinib simultaneously targets multiple signaling pathways responsible for the

disease pathogenesis in both the immune cells and epithelial cells. SYK-JAK inhibition with gusacitinib not only modulates Th2, Th22 cytokines to target atopic dermatitis, but also Th1 and Th17 cytokines, thereby targeting indications such as chronic hand eczema that have allergic and irritant disease drivers. This multi-pathway approach holds promise for treating a wide range of dermatological diseases such as atopic dermatitis, psoriasis, chronic hand eczema, and hidradenitis suppurative, and inflammatory conditions including systemic lupus erythematosus, ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis.

### **About Asana BioSciences, LLC**

Asana BioSciences is a clinical stage biopharmaceutical company based in Lawrenceville, NJ. Asana is focused on discovery and development of novel targeted investigational medicines in immunology/inflammation and oncology.

Asana's lead oncology asset ASN007 is a potent inhibitor of the extracellular-signal-regulated kinases ERK1 and ERK2, which are key players in the RAS/RAF/MEK/ERK (MAPK) signaling pathway. ASN007 has completed Phase 1 dose-finding and is in clinical development in patients with advanced solid tumors, including RAF- and RAS-mutant cancers (NCT03415126).

ASN003 is a selective inhibitor of BRAF and PI3 kinases. Dual targeting of RAF and PI3K pathways has the potential to overcome and/or delay acquired resistance to selective RAF inhibitors. ASN003 is in Phase 1 development in patients with BRAFV600 mutated metastatic melanoma, metastatic colorectal and advanced non-small cell lung cancer (NCT02961283).

ASN004 is an Antibody Drug Conjugate that targets the 5T4 oncofetal antigen, which is expressed in a wide range of malignant tumors but has very limited expression in normal tissues. ASN004 demonstrates robust and durable antitumor activity after single administration in multiple human tumor xenograft models. A First-in-Human Phase 1 trial is being planned.

Asana is also developing ASN009, a highly selective antagonist of the purinergic P2X3 ion channel that is activated by extracellular ATP and involved in various pain, urological and respiratory disease conditions. Preclinical proof-of-concept has been demonstrated with ASN009 in a cough model. ASN009 is currently in preclinical development.

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