

## **Chromocell and Astellas Announce FDA Fast Track Designation and First Subject Dosing with Lead Candidate CC8464/ASP1807 for the Management of Neuropathic Pain Associated with iSFN**

*Expedited program could facilitate the development of novel Na<sub>v</sub>1.7 inhibitor*

**North Brunswick, N.J. and Tokyo**, October, 12, 2016 – Chromocell Corporation and Astellas Pharma Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the development program of the drug candidate CC8464/ASP1807, for the management of neuropathic pain associated with idiopathic small fiber neuropathy (iSFN). In 2015, Chromocell and Astellas entered into a license and collaboration agreement for the development and commercialization of CC8464/ASP1807 for the management of neuropathic and other pain indications.

Chromocell submitted the IND for CC8464/ASP1807 in July, 2016, and recently dosed the first subject in a Phase I clinical trial to evaluate the safety, tolerability, and pharmacokinetics of the oral formulation of CC8464/ ASP1807.

The FDA's Fast Track program is intended to help ensure that therapies intended for serious or life threatening conditions that address unmet medical needs are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. Features of Fast Track designation include actions that expedite development and review including frequent interactions with the FDA Division responsible for review.

Christian Kopfli, Chief Executive Officer of Chromocell, said, "This is an important milestone for the CC8464/ASP1807 program, following the FDA's recent acceptance of Chromocell's investigational new drug (IND) application. Collaboration with the regulatory agency through programs like Fast Track provides further momentum as we advance our lead analgesic drug candidate into clinical trials. It is also a testimony to the close and productive alliance with Astellas. We hope that this development will help us bring a new potential treatment alternative to opioids for patients suffering from peripheral neuropathic pain associated with iSFN as quickly as possible."

Bernhardt G. Zeiher, M.D., President, Development, Astellas said, "We are pleased that Fast Track designation was granted by the FDA as it recognizes the importance of accelerating the development in the neuroscience area. This is a testament to our commitment to closely collaborate with Chromocell in addressing this unmet medical need."

### **About CC8464/ASP1807**

Chromocell's lead compound, CC8464 (Astellas' Development Code:ASP1807), is an oral, potent, highly selective, peripherally-restricted inhibitor of Na<sub>v</sub>1.7, which has been shown to be efficacious in multiple animal models of human neuropathic and inflammatory pain. Na<sub>v</sub>1.7 is an ion channel involved in pain transmission. CC8464 was developed using Chromocell's proprietary drug discovery platform, Chromovert®.



### About Chromocell Corporation

Chromocell is a life sciences company which improves consumer products and patient lives through breakthrough science and technologies. Chromocell is focused on the discovery and development of therapeutics and flavors through the use of pioneering Chromovert® technology. Chromovert® technology enables Chromocell to use rare cells ideally suited for effective high-throughput screening. Chromocell's therapeutics pipeline is currently focused on analgesics and rare diseases, where Chromovert® technology has proven highly effective in the rapid identification of potential new drug candidates, as well as discovery and development of novel flavor ingredients and natural taste enhancers.

### About Astellas Pharma Inc.

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at [www.astellas.com/en](http://www.astellas.com/en).

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