

Astellas: Reshaping research framework to enhance the ability to generate innovative drugs

Tokyo, Japan, May 14, 2013 - [Astellas Pharma Inc.](#) (Tokyo : 4503, President and CEO: Yoshihiko Hatanaka, hereinafter called “Astellas”) today announced plans to reshape its research framework by introducing new initiatives to further enhance the ability to generate innovative drugs.

By optimizing the allocation of resources for its research and development function, Astellas aims to achieve the following objectives: i) Utilize more external capabilities and resources; ii) Undertake initiatives related to new therapeutic areas and innovative technologies including regenerative medicine and vaccines; iii) Accelerate the development of Astellas' promising preclinical pipeline; and iv) Ensure sufficient investment in late-stage clinical pipeline.

Details of specific initiatives are outlined below.

(1) Establish Astellas Innovation Management (AIM)

In order to enhance the process of screening external opportunities to strengthen innovation during the preclinical development stage, activities that are currently undertaken by multiple departments, including Astellas Venture Management LLC (AVM), will be integrated with the establishment of Astellas Innovation Management (AIM), scheduled for October 2013. By integrating functions under AIM, Astellas will be able to make continued use of its strengths in AVM, while drawing more widely and systematically on innovation opportunities arising in areas such as bio-venture companies and academia.

(2) Enhance research management

The research units for each therapeutic area will be assigned broader authority and responsibility to promote the autonomy and agility of each unit. Through a closer alliance with AIM, the active integration of internal and external knowledge and other such activities, Astellas will transform the way it carries out research to further employ cutting-edge science, including new therapeutic areas and innovative technologies.

(3) Introduce multiple-path project management

The current “Multi-Track R&D” process will be implemented at an earlier stage of the research process. Highly prioritized research projects will be classified as “Fast Track”, and research and development time will be minimized through the focused investment of both capabilities and resources. In addition, “Ex. (External/Expedite/Exploratory) Track” approach will be applied to

unique and challenging projects, for the purpose of obtaining POC (Proof of Concept) in a more efficient manner through the flexible use of internal and external capabilities and resources.

(4) Optimize research functions

The reshaping initiatives outlined below will be carried out to reallocate resources and realize operational excellence.

① Close/scale back research functions

(Scheduled during FY2013: Some functions are scheduled for transfer to the Tsukuba Research Center)

- OSI Pharmaceuticals, LLC (US): To be closed
- Perseid Therapeutics LLC (US): To be closed
- Astellas Research Institute of America LLC (US): To be scaled back (focus on CNS therapies)

② Cease in-house fermentation research

③ Close the Kashima facility in Osaka (scheduled during FY2015)

The multiple functions of the Kashima facility will be integrated and transferred to appropriate sites, including the Tsukuba Research Center.

The extraordinary losses of approximately JPY 11 billion have been accounted in the forecasts for the fiscal year ending March 2014 to reflect these initiatives.

In conjunction with the reshaping of Astellas' research framework, in April 2014, functions including the Clinical Development, QA (Quality Assurance) & RA (Regulatory Affairs) and Pharmacovigilance currently located in Itabashi-ku, Tokyo, will be relocated and consolidated closer to Astellas' headquarter in Nihonbashi, Chuo-ku, Tokyo as part of initiatives to pursue excellence in Astellas' operation model.

Through this reshaping research program, Astellas will enhance its ability to generate innovative drugs by deploying cutting-edge science (Best Science), accessing to distinguished internal and external talents (Best Talent), and utilizing the optimal research environment (Best Place).

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