



Announcement Concerning Signing of License and Distribution Agreement for SP-02 (darinaparsin injection) in Latin America

Tokyo, Japan, August 17, 2018 – Solasia Pharma K.K. (TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter “Solasia”) announced today that Solasia and HB Human BioScience SAS (Headquarters: Bogota, Colombia, hereinafter “HB”) have entered into an exclusive license agreement pertaining the development and commercialization of SP-02 (Generic name: Darinaparsin, hereinafter “darinaparsin”) in Latin America which Solasia holds the global rights to develop and commercialize and is currently conducting clinical development in Asia. The licensed territory to HB includes Colombia, Peru, Ecuador, Venezuela, Chile, Panama, Costa Rica, and Guatemala (hereinafter collectively “Latin America”).

Solasia obtained an exclusive worldwide license to develop and commercialize darinaparsin from ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP, Headquarters: Massachusetts, US), and has been conducting Phase II Pan-Asian study with the intended indication as treatment of relapsed and refractory PTCL (herein after “PTCL”). Currently, Solasia is conducting the Phase II Pan-Asian study in Japan, Korea, Taiwan and Hong Kong, as a pivotal(final) study, expecting to complete the study within this year, and release the results in 2019. Upon completion and the results being satisfactory, the NDA will be submitted to the authority. Furthermore, once good results in the PTCL study becomes available, expansion of indication to other cancers such as hematologic cancers are planned.

For the commercialization of darinaparsin in Japan, Solasia have already entered into an exclusive license agreement with Meiji Seika Pharma Co. Ltd., and this will be the second license agreement for this product. Once the result of pivotal study becomes available, Solasia plan to actively seek licensing partners in areas such as EU and US.

Under the terms of the agreement, with the approval in Japan as a trigger, HB will initiate actions necessary to obtain approval and commercialize darinaparsin in Latin America. Solasia will receive signing fee and milestone payments tied to development progression from HB (hereinafter, “development milestone”) and also receive profit share after commercial launch of the product tied to net profit of HB (hereinafter, “profit share”). The term of the agreement is structured with an emphasis on profit share portion relative to development milestone, since the added value in pharmaceutical industry is created mostly after the launch of the product.

The impact of executing this agreement is mostly concentrated post product launch in Latin America. Thus, the impact of executing this agreement is immaterial to the current fiscal year’s financial forecast, and no change in financial forecast will be announced as of now.

About SP-02 (darinaparsin):

Darinaparsin is a novel mitochondrial-targeted agent (organoarsenic) being developed for the treatment of various hematologic and solid cancers. In a US Phase II study, Darinaparsin demonstrated evidence of clinical activity in lymphoma, in particular PTCL. Furthermore, the Phase I clinical study done in US, and the Pan-Asian Phase I clinical study both demonstrated positive efficacy and safety. SP-02 have been granted orphan drug designation in US and EU.



About Solasia Pharma K.K (Solasia):

Solasia is a specialty pharmaceutical company based in Asia, with a mission of "Better Medicine for a Brighter Tomorrow". In order to address the unmet medical needs within the oncology area, we develop innovative medicines to contribute to the patient's healthy living and to provide treatment options for the healthcare providers.

Additional information is available at <http://www.solasia.co.jp/en/>

About Human BioScience SAS (HB):

HB is a Latin American Pharmaceutical Company based in Bogotá Colombia dedicated to the Research & Development and Commercialization of innovative pharmaceutical products with a focus on the treatment of high risk patients suffering from Catastrophic and Orphan Diseases. HB not only imports innovative treatments from recognized laboratories around the world but also focuses in in-house development of new molecules to create therapeutic options for patients in the pharmaceutical markets of Latin America. Towards this end, HB works closely with a great team of professionals who apply their knowledge and creativity to produce and provide better and safer medicines to heal or prolong the life of thousands of patients throughout the region. Today HB counts with a broad portfolio of biologic and chemical synthesis drugs dedicated to the treatment of neglected and catastrophic diseases; specializing in different therapeutic areas such as Oncology, Organ Transplantation, Antibiotics, HIV AIDS Therapies, and Orphan Drugs, as well as running a robust named patient early access drug delivery program.

For details please refer to: <http://www.hbhumanbioscience.com/>

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