Solasia Announces Initiation of Darinaparsin Injection (SP-02) Phase 1 Study

Solasia Pharma K.K. (Minato-ku, Tokyo) announced today that enrollment of a Phase I clinical trial evaluating the safety and tolerability of darinaparsin injection (SP-02L) for the treatment of peripheral T-cell lymphoma (PTCL), has commenced in Japan.

Darinaparsin is a novel mitochondrial-targeted agent being developed for the treatment of various hematologic and solid cancers. In several studies conducted in the US and other countries, darinaparsin injection has demonstrated good tolerability and safety. In addition, a Phase II study of darinaparsin injection in the US, demonstrated clinical responses in lymphoma, in particular PTCL.

Solasia has an exclusive license from ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) to develop and commercialize darinaparsin, in both intravenous and oral forms, across Asia including Japan, China, Hong Kong, Macau, Republic of Korea, Taiwan, Singapore, Australia, New Zealand, Malaysia, Indonesia, Philippines and Thailand.

Solasia also announced it has entered into a collaboration agreement with ACRONET, a leading CRO in Japan, and a wholly-owned subsidiary of ITOCHU Corporation. Both companies will work closely together on the Phase I study of darinaparsin in Japan.

Steven Engen, CEO, commented, “Initiation of this study is an important milestone for Solasia. Based on the attractive profile of darinaparsin, Solasia’s first oncology therapeutic, we believe this drug has the potential to become an important new therapy for patients suffering from lymphoma.”

About Darinaparsin:

Darinaparsin is a novel mitochondrial-targeted agent being developed for the treatment of various hematologic and solid cancers. In a Phase II study, darinaparsin injection demonstrated clinical responses in lymphoma, in particular peripheral T-cell lymphoma (PTCL). Darinaparsin was designated Orphan Drug Designation in the U.S. and Europe as a treatment of PTCL, and Solasia intends to seek similar status in Japan. An oral form is in a Phase I trial for solid tumors.
About Solasia Pharma, K.K.:

Solasia Pharma K.K. (Tokyo, Japan) was formed in November 2006 by MPM Capital and ITOCHU Corporation to address unmet needs for important new Western oncology therapies throughout Asia. The company's mission is to expedite patient access to unique oncology therapies through aggressive development and specialized commercialization throughout Japan, China and other Asian countries. In May 2008, Solasia acquired Asian rights to Sancuso (extended release granisetron transdermal patch) from ProStrakan Group plc. Solasia is conducting Sancuso clinical development in China, and expects to complete studies required for filing a New Drug Application (NDA) in China in 2012. To date, Solasia has raised approximately $29 million in Series A and B financing.

About ACRONET:

ACRONET, a member of ITOCHU group (100% subsidiary), the forerunner as a biostatistics and data management service provider in Japan, provides full service of clinical development including monitoring, data management and statistical analysis. In addition to the broad experience in a primary care, ACRONET has a specialized department of oncology, accumulating the special know-how of anticancer drug development.

Further information about ACRONET is available at http://www.acronet.jp/en/

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of a diverse portfolio of cancer therapeutics. The Company is currently focused on several clinical programs.

Palifosfamide (Zymafos™ or ZIO-201) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide and is currently in a randomized, double-blinded, placebo-controlled Phase 3 trial with palifosfamide administered intravenously for the treatment of metastatic soft tissue sarcoma in the front-line setting. The Company is also currently conducting a Phase 1 study of palifosfamide in combination with standard of care for addressing small cell lung cancer; an oral form of palifosfamide continues in preclinical study.
Darinaparsin (Zinapar™ or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) currently in a solid tumor Phase I study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

Indibulin (Zybulin™ or ZIO-301) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase 1/2 in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, both of which are currently in Phase 1. ZIOPHARM's operations are located in Boston, MA and Germantown, MD with an executive office in New York City.

Further information about ZIOPHARM may be found at www.ziopharm.com.