HEALTH CANADA APPROVES INQOVI® (DECITABINE AND CEDAZURIDINE) ORAL THERAPY FOR TWO TYPES OF BLOOD CANCERS, MDS AND CMML

- *Oral drug can be taken at home, which may enable some patients to avoid some hospital visits*
- *Treatment can induce complete remission and reduce blood transfusion needs for patients*[i]

OAKVILLE, ON, OCTOBER 8, 2020 – Taiho Pharma Canada, Inc., the Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announces that Health Canada approved INQOVI® as the first and only orally administered hypomethylating agent for the treatment of adults with intermediate-1, intermediate-2 and high-risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML),[ii] two blood malignancies. INQOVI was developed by Astex Pharmaceuticals, a sister company of Taiho and will be available in Canada.

"INQOVI offers selected MDS patients an effective oral treatment alternative to the current standard 7 days of subcutaneous injections administered in a cancer centre every month," says Dr. Rena Buckstein, Hematologist Oncologist at the Odette Cancer Centre at Sunnybrook Health Sciences Centre, Toronto, Ontario. "Having an oral option is very important for patients who cannot travel and is particularly significant during the COVID-19 pandemic when we try to minimize hospital visits to protect patients and medical staff."

"Canadian oncologists and patients were involved in the clinical development program for INQOVI with several clinical study sites," said Dr. Mohammad Azab, President and Chief Medical Officer of Astex Pharmaceuticals. "We are thrilled that INQOVI is now available for healthcare professionals to prescribe to their patients across Canada living with MDS and CMML."

About MDS & CMML

Myelodysplastic syndromes (MDS) are a group of diseases in which the bone marrow does not make enough healthy mature blood cells. The immature blood cells, called blasts, do not work properly. They build up in the bone marrow and the blood. As a result, there are fewer healthy red blood cells, white blood cells and/or platelets. MDS is treated as a form of blood cancer.[iii] It has been estimated there may be between 10,000 and 40,000 Canadians 65 and over who have been diagnosed with, or are living with, MDS. Among adults aged 65 and older, the incidence has been estimated to range from 75 to 162 per 100,000.[iv]

Chronic myelomonocytic leukemia (CMML) is a type of cancer that starts in blood-forming cells of the bone marrow and invades the blood. It mainly affects older adults.[v] CMML is an uncommon blood cancer that affects approximately three in 100,000 individuals in the United States each year.[vi]

"This announcement is good news for people living with MDS and CMML, says Cindy Anthony, Executive Director of the Aplastic Anemia & Myelodysplasia Association of Canada (AAMAC). “We welcome new treatments that can be taken at home to reduce hospital visits, and which can also induce complete remission for patients." AAMAC is a support network for Canadian patients, family members, friends, and healthcare providers dealing with aplastic anemia, myelodysplasia and paroxysmal nocturnal hemoglobinuria. AAMAC provides educational opportunities, research funding and nursing scholarships.

About INQOVI and Accelerated Project ORBIS

INQOVI is a novel, orally administered, fixed-dose combination of the approved anti-cancer DNA hypomethylating agent, decitabine, together with cedazuridine,[vii] an inhibitor of cytidine deaminase.[viii] By inhibiting cytidine deaminase in the gut and the liver, INQOVI is designed to allow for oral delivery of decitabine over five days in a given cycle to achieve equivalent systemic exposure to IV decitabine.[ix] The Health Canada approval was based on data from the ASCERTAIN phase 3 study and supporting phase 2 clinical studies. INQOVI was developed by Astex Pharmaceuticals, Inc., a sister company of Taiho Pharma Canada, Inc.

The review and approval of INQOVI was conducted under the Project ORBIS initiative with simultaneous submission and regulatory review in Canada, the United States and Australia**.** The ORBIS project enabled a more efficient review and completion of assessment in a timely manner where the outcome is expedited, thus enabling the timely availability of this important oral alternative to patients in participating countries.

“The approval of INQOVI was made possible through Project Orbis, an international health authority collaboration aimed at providing earlier access to patients,” said Ross Glover, General Manager at Taiho Canada, Inc. “The accelerated approval of INQOVI by Health Canada brings new advances for patients living with these blood disorders, allowing them to take their HMA therapy from the convenience and safety of their home, freeing patients from the burden of onsite injections”.

About Taiho Pharma Canada, Inc. (Canada)

Taiho Pharma Canada, Inc., the Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), is located in Oakville, Ontario and managed by Taiho Oncology, Taiho’s U.S. R&D and commercial operations, based in Princeton, New Jersey. Advanced technology, dedicated researchers, and state of the art facilities are helping Taiho define the way the world treats cancer. It’s our work; it’s our passion; it’s our legacy. Commercialization of oral INQOVI in Canada will be conducted by Taiho Pharma Canada, Inc.

About Astex, Taiho, and Otsuka

Astex is a leader in innovative drug discovery and development, committed to the fight against cancer. Astex is developing a proprietary pipeline of novel therapies and has multiple partnered products in development under collaborations with leading pharmaceutical companies. Astex is a wholly owned subsidiary of Otsuka Pharmaceutical Co. Ltd., based in Tokyo, Japan.

Taiho Oncology, Inc., is a subsidiary of Taiho Pharmaceutical Co., Ltd. and an indirect subsidiary of Otsuka Holdings Co., Ltd. Taiho has established a world-class clinical development organization that works urgently to develop innovative cancer treatments and has built a commercial business in the U.S. Taiho has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents.

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: "Otsuka–people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

Astex Pharmaceuticals, Inc.; Taiho Oncology, Inc.; and Otsuka Pharmaceutical Co., Ltd. are all members of the Otsuka group of companies.

For more information about:
Taiho Pharma Canada, please visit: https://www.taihopharma.ca/en/.
Astex Pharmaceuticals, Inc. please visit: https://www.astx.com
Otsuka Pharmaceutical, please visit: https://www.otsuka.co.jp/en/
Taiho Pharmaceutical, please visit: https://www.taihooncology.com/

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INQOVI® (cedazuridine and decitabine) is indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups.[x]

The ASCERTAIN phase 3 study evaluated the five-day, decitabine exposure equivalence between oral INQOVI and intravenous decitabine. The safety and efficacy of INQOVI was also assessed in the clinical studies. The phase 1 and phase 2 clinical study results have been published in Lancet Haematology[viii] *and Blood,*[xi] *respectively. The phase 3 ASCERTAIN study data was presented at the American Society of Hematology (ASH) Meeting in Orlando, Florida, in December 2019 by Dr. Garcia-Manero.*[xii]

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[iv] https://www.llscanada.org/sites/default/files/National/CANADA/Pdf/InfoBooklets/Blood_Cancer_in_Canada_Facts_%26_Stats_2016.pdf. Accessed July 3 2020.

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