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Otsuka Pharmaceutical Co., Ltd.

Taiho Pharmaceutical Co., Ltd.

Taiho announces simultaneous regulatory approvals by U.S. FDA and Health Canada of INQOVI®, an oral hypomethylating agent (HMA) therapy for MDS and CMML

- First orally administered hypomethylating agent approved by the FDA and Health Canada
- An option for patients with MDS and CMML to potentially reduce the number of office visits and to take their medication from the convenience and comfort of their homes

Taiho Pharmaceutical Co., Ltd. (Taiho) announces that the U.S. Food and Drug Administration (FDA) and Health Canada have approved INQOVI® (decitabine and cedazuridine) tablets for intermediate and high-risk MDS (myelodysplastic syndromes) and CMML (chronic myelomonocytic leukemia), two blood malignancies.

INQOVI is the first and only orally administered hypomethylating agent approved in the U.S. and Canada for the treatment of MDS and CMML.

Approval in the U.S. and Canada was based on data from the ASCERTAIN phase three study and supporting phase one and two clinical studies. The ASCERTAIN phase three 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 announcement is also being issued by Taiho's North American subsidiary, Taiho Oncology, Inc. in the U.S.; by Astex Pharmaceuticals, Inc. in the U.S.; and by Otsuka Pharmaceutical Co., Ltd. in Japan. The three companies are all part of the Otsuka group of companies.