WellMarker Bio Co., Ltd
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WellMarker Bio—developing fit-for-purpose biomarkers and novel therapies for cancer

Seoul-based WellMarker Bio is developing a deep pipeline of first-in-class drugs guided by comprehensive biomarker analysis.

WellMarker Bio Co., Ltd (WMBIO), the first company to be spun out from the renowned Asan Medical Center, Korea's largest hospital, focuses on the development of new anticancer drugs derived from comprehensive biomarker analysis. Since its founding in 2016, WMBIO has developed first-in-class drugs for indications including colon cancer, liver cancer, non-small-cell lung cancer (NSCLC) and other cancers (Fig. 1). Having access to a wide array of patient samples from Asan and using predictive biomarkers to guide therapeutic development in innovative ways has allowed WMBIO to rapidly move its assets from exploratory to preclinical and now into early clinical stages. WMBIO's lead asset, WM-S1, is a small-molecule for colon cancer slated to go into a phase 1 clinical trial in the USA in Q3, 2020, and the company is exploring additional indications for the compound.

One of WMBIO's strengths is the company's extensive network of both national and international collaborations to advance its drug development programs. These collaborations augment WMBIO's in-house capabilities, which include a MediChem Research Center, a CMC Center, a Bio-Research Center and a Clinical Development Center.

According to Dong-Hoon Jin, CEO of WMBIO, "In the past, cancer patients were given an expensive anticancer drug yet the efficacy of the drug would be low. Our job is to increase the number of efficacious drugs through the use of predictive biomarkers."

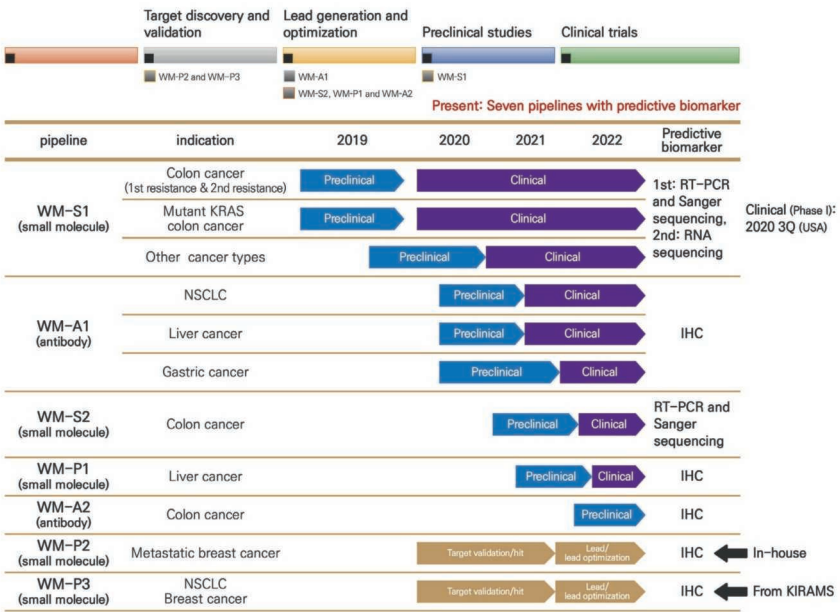

Fig. 1 | WellMarker Bio Co., Ltd is developing new anticancer drugs. The company has first-in-class drugs for indications in solid tumors such as colon cancer, liver cancer and non-small-cell lung cancer (NSCLC). IHC, immunohistochemistry; RT-PCR, reverse transcription polymerase chain reaction.

Taking the lead

WMBIO's lead asset, WM-S1, shows potent in vitro enzyme inhibitor activity, high in vitro anticancer activity and strong anticancer efficacy in xenograft models and PDX models. Preclinical studies have been completed for WM-S1 in collaboration with Charles River. The preclinical data suggest it could be used as a monotherapy for Erbitux (cetuximab) non-responder colon cancer and other cancer types. Phase 1 studies for WM-S1 are planned for Q3, 2020 in the USA, and WMBIO is collaborating with Cytogen on the development of a method to detect the predictive biomarker in a liquid biopsy sample. This program is being carried out with support from KDDF (the Korean Drug Development Fund), and WMBIO is in conversations with global pharmaceutical companies for a potential out-licensing deal.

WMBIO's second lead asset, WM-A1, is a therapeutic antibody with immunotherapeutic effects in NSCLC and antitumor effects in gastric cancer and liver cancer. The program is in the lead optimization stage with support from KDDF.

Other predictive biomarker-based assets in WMBIO's pipeline include WM-S2, WM-A2, WM-P1, WM-P2 and WM-P3. The company is investigating the efficacy of these drugs in vitro and in vivo, and validating the predictive biomarkers in samples from Korean and Caucasian patients with cancer.

"Everybody has a different genetic makeup, which determines the efficacy of a drug for individual patients. By analyzing a cancer patient's samples, we can predict a drug's efficacy based on the gene expression profile following treatment with a particular anticancer drug," said Jin. "From a regulatory perspective, drugs without biomarkers have an 8.7% chance of getting final approval from the FDA, but those with companion biomarkers have a 26.7% chance of being approved."

Taking a collaborative approach

WMBIO's research and development strategy is to focus mainly on drug discovery and early-stage development of lead compounds to build a deep and wide pipeline of products it can carry up to and through phase 1 clinical trials. Once a drug candidate is at that stage, WMBIO seeks co-development or licensing partners among global pharmaceutical companies or other relevant players.

Current collaborations for WMBIO's WM-S1 program include Cytogen, Charles River, Asan's New Drug Development Center for the performance of DMPK studies, and C&R Research and Covance for the design and supervision of clinical studies. For the WM-A1 programs, WMBIO has partnered with Y-biologics for the development of therapeutic antibodies.

Beyond establishing collaborations for the development of WMBIO's new drug leads and companion diagnostics, WMBIO has started building a network of international institutions to develop and validate the company's existing biomarkers and discover potential new ones for universal application. First memoranda of understanding have been signed with top national medical institutions in Ukraine.

CONTACT
Jai-Hee Moon, Team Leader/
R&BD Planning Team
WellMarker Bio Co., Ltd
Seoul, Republic of Korea
Tel: +82 2 6952 1637
Email: jhmoon@wmbio.co