BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Gilead to acquire Forty Seven for $4.9 B

04 March 2020 | News

Transaction Supports Gileadâ??s Strategic Focus in Oncology and Gives Access to Potential New First-in-Class Program and Innovative Pipeline



Gilead Sciences, Inc. and Forty Seven, Inc. announced that the companies have entered into a definitive agreement pursuant to which Gilead will acquire Forty Seven for $95.50 per share in cash. The transaction, which values Forty Seven at approximately $4.9 billion, was unanimously approved by both the Gilead and Forty Seven Boards of Directors and is anticipated to close during the second quarter of 2020, subject to regulatory approvals and other customary closing conditions.

Through the addition of Forty Seven's investigational lead product candidate, magrolimab, the acquisition will strengthen Gilead's immuno-oncology research and development portfolio. Magrolimab is a monoclonal antibody in clinical development for the treatment of several cancers for which new, transformative medicines are urgently needed, including myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) and diffuse large B-cell lymphoma (DLBCL). The investigational therapy targets CD47, a "do not eat me" signal that allows cancer cells to avoid destruction thereby permitting the patient's own innate immune system to engulf and eradicate those cancer cells. Forty Seven presented promising results of a Phase 1b study of magrolimab in patients with MDS and AML at the American Society of Hematology meeting in December 2019. Magrolimab has the potential to be a first-in-class therapy.

"This agreement builds on Gilead's presence in immuno-oncology and adds significant potential to our clinical pipeline," said Daniel O'Day, Chairman and Chief Executive Officer of Gilead Sciences. "Magrolimab complements our existing work in hematology, adding a non-cell therapy program that complements Kite's pipeline of cell therapies for hematological cancers. With a profile that lends itself to combination therapies, magrolimab could potentially have transformative benefits for a range of tumor types. We are looking forward to working with the highly experienced team at Forty Seven to help patients with some of the most challenging forms of cancer."

"This is an exciting day for patients who may one day benefit from future anti-CD47 therapies and other immuno-oncology treatments based on our research and an exciting time for Forty Seven as this allows us to achieve our vision of helping patients defeat their cancer," commented Mark McCamish, MD, PhD, President and Chief Executive Officer of Forty Seven. "We are pleased to join Gilead and believe that by combining our scientific expertise with Gilead's strength in developing treatments that modify the immune system, we will be able to more rapidly advance our therapies."

Magrolimab

Forty Seven is initially studying magrolimab in patients with MDS and AML. Additional studies are ongoing in non-Hodgkin lymphoma (NHL) and solid tumors. Magrolimab has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of MDS and AML, and for the treatment of relapsed or refractory DLBCL and follicular lymphoma, two forms of B-cell NHL. Magrolimab has also been granted Orphan Drug designation by the FDA for the treatment of MDS and AML and by the European Medicines Agency for the treatment of AML.

More than 400 patients have received the compound to date through clinical trials.

Ongoing Phase 1b Clinical Trial

In December 2019, Forty Seven presented promising results of a Phase 1b trial evaluating magrolimab in combination with azacitidine in untreated patients with higher risk MDS and untreated patients with AML, who are ineligible for induction chemotherapy. This has led to the initiation of a potential registrational cohort in MDS. All patients received a 1 mg/kg priming dose of magrolimab, coupled with intrapatient dose escalation to mitigate on-target anemia. Patients were then treated with full doses of azacitidine and magrolimab maintenance doses of 30 mg/kg weekly.

As of the data cutoff of November 18, 2019, 62 patients had been treated with the combination in the Phase 1b portion of the trial, including 35 patients with MDS and 27 patients with AML.

Clinical Activity Data

As of the data cutoff, 46 patients were evaluable for response assessment, including 24 patients with untreated higher-risk MDS and 22 patients with untreated AML, who were ineligible for induction chemotherapy.

- In higher-risk MDS, the overall response rate (ORR) was 92 percent, with 12 patients (50 percent) achieving a complete response (CR), eight patients (33 percent) achieving a marrow CR and two patients (8 percent) achieving hematologic improvement. Two patients (8 percent) had stable disease.
- In untreated AML, the ORR was 64 percent, with nine patients (41 percent) achieving a CR, three patients (14 percent) achieving a CR with complete blood count recovery (CRi) and one patient (5 percent) achieving a morphologic leukemia-free state (MLFS). Seven patients (32 percent) had stable disease and one patient (5 percent) had

progressive disease.

- The median time to response among MDS and AML patients treated with the combination was 1.9 months.
- Median duration of response and median overall survival have not been reached for either MDS or AML patients, with a median follow-up of 6.4 months (range 2.0 to 14.4 months) for MDS and 8.8 months (range 1.9 to 16.9 months) for AML.

Safety Data

As of the data cutoff, the combination of magrolimab and azacitidine was well-tolerated, with no evidence of increased toxicities compared to azacitidine alone. Adverse events (AEs) were consistent with prior clinical experience. No deaths were observed in the first 60 days on combination treatment and only one patient out of 62 (1.6 percent) discontinued treatment due to a treatment-related AE.