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CytoDyn, Inc.

CYDY: Price: $0.45; Market Cap (M): $162
Rating: Buy; Price Target: $1.50

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Senior Science Advisor Appointed; Near-Term Revenue Opportunity; Reiterate Buy

Click here for complete report and disclosures

Exploring leronlimab in both HIV prophylaxis and cure. Yesterday, Cytodyn announced the appointment of Dr. Jonah Sacha, Ph.D. as senior science advisor. Dr. Sacha serves on the National Institutes of Health (NIH) Office of AIDS Research Advisory Council, and leads a research laboratory in the Vaccine and Gene Therapy Institute and Oregon National Primate Research Center at the Oregon Health & Science University. Dr. Sacha's studies have led CytoDyn to the signing of a Memorandum of Understanding with the Thai Red Cross AIDS Research Centre last month. In his newly appointed role at Cytodyn, Dr. Sacha will lead the development of leronlimab as a potential therapeutic for HIV Pre-Exposure Prophylaxis (PrEP) and HIV remission (or cure). We note that, as published in *Nature* in April 2019, an adult infected with HIV-1 underwent allogeneic hematopoietic stem-cell transplantation (HSCT) for Hodgkin's lymphoma using cells from a CCR5Δ32/Δ32 donor, and experienced sustained HIV remission for 18 months after anti-retroviral therapy (ART) was discontinued (the patient remained on ART for 16 months post-transplant). This is the second documented patient that has achieved an effective HIV cure, following the "Berlin Patient" a decade ago. Both patients received an HSCT from donors who have two mutated copies of the CCR5 allele and are unable to express the CCR5 receptor. Specifically, the experience of the second patient suggests that a single allogeneic HSCT with homozygous CCR5Δ32 donor cells may be sufficient to achieve HIV-1 remission with reduced intensity conditioning and no irradiation, and blocking CCR5 expression could be a feasible strategy to achieve HIV-1 remission. Leronlimab is a humanized IgG4 mAb that blocks CCR5, thus mimicking the effect of preventing CCR5 expression, and thus could be used for HIV PrEP and remission. Importantly, potential use of leronlimab in approaches for PrEP and/or remission could provide additional label expansion opportunities, in our view, if leronlimab is approved as a combination therapy with ART first. In the wake of this update, we reiterate our Buy rating and $1.50 price target.

Near-term revenue in diagnostics. Last week, the company announced a non-binding agreement with IncellDX, Inc. (private) for a diagnostic license and supply agreement for the PA-14 antibody (the diagnostic designation of the murine version of PRO 140) and leronlimab (PRO 140, humanized PA-14). The PRO 140 material used for the PA-14 diagnostic test is non-commercial grade product in storage, and thus allows the company to potentially realize value from product that would have been discarded. Of note, this diagnostic test is required for potential future commercial use of leronlimab. We expect the company to finalize the agreement this month and start recognizing revenue in August 2019, or 1Q FY2020.

Leronlimab regulatory filing as a combination therapy for HIV on track for completion in 3Q19. In March 2019, Cytodyn filed the non-clinical portion of its Biologics License Application (BLA) with the FDA. The non-clinical portion constitutes the first of three sections of the BLA submission for the 700mg leronlimab weekly dose as a combination therapy with HAART for HIV-infected patients. Leronlimab is a humanized IgG4 mAb that blocks CCR5 receptor and prevents HIV-1 from entering and infecting immune cells. The FDA has granted Fast Track designation for leronlimab in HIV. The rolling review process allows the company to submit individual sections of the BLA for assessment as they are completed. The clinical and chemistry, manufacturing and controls (CMC) sections of the leronlimab BLA are slated to be filed in the coming months. We believe all three sections of the BLA submission could be filed by 3Q19 and potential FDA approval could be obtained in 1H20.

Monotherapy at 525mg achieves 95% response rate in HIV. In May 2019, the company reported new data on leronlimab as a single agent for maintenance of HIV viral load suppression (HIV-1 RNA <50 copies/ml). Data showed that the 525mg dose of leronlimab achieved 95% response rate after the first 10 weeks of monotherapy. Over 110 patients have reached almost one year of suppressed viral load with monotherapy on the original dose of 350mg or higher dosages. Half-life of leronlimab is confirmed at approximately 10 days versus the previous understanding of approximately three days. These data suggest that the 525mg dose is no less efficacious than the 700mg dose, and could help the company design the pivotal Phase 3 monotherapy trial for label expansion after the potential approval of leronlimab for HIV as a combination therapy with highly active anti-retroviral therapy (HAART).

Valuation and risks. Our 12-month price target is derived from an estimated market value of the firm at $585M. It includes a discounted cash flow-based asset value of $592M for leronlimab in the HIV indication alone, with a 15% discount rate, 2% terminal growth rate, 80% probability of approval, and excluding $8M debt. Assuming 391M shares outstanding at the end of May 2020, this translates to a per share value of approximately $1.50. Risks include, but are not limited to: (1) failure of leronlimab in clinical trials; (2) failure of leronlimab to secure regulatory approval; (3) failure of leronlimab to achieve commercial success due to market size, penetration rate, and/or competition; and (4) dilution risk.

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