

Argos Therapeutics (ARGS)

Overweight

Don't be Fooled by VL - 004 Immune Data; May Be Positive for Arcelis in Oncology

CONCLUSION

Argos reported that the Phase IIb study of dendritic cell immunotherapy AGS-004 for treating HIV has missed its primary endpoints (viral load reduction in patients off ART during a scheduled treatment interruption, TI). That said, the trial generated positive immune responses that were rigorously defined and notable in this immune-suppressed patient population, which provide encouraging incremental read-through to the use of the Arcelis platform in oncology, in our view. In addition to the company telegraphing that it intended further trials in HIV with different non-TI protocols, we previously published that we considered the trial to be a "high bar" and therefore didn't include '004 in our valuation.

- **Bigger picture for ARGS shares.** While we expect shares to trade down due to increased scrutiny of the Arcelis platform, the outcome doesn't change our expectations for the ongoing Phase III for '003 in renal cell cancer, or the broader platform. Additionally, as the '004 program has been externally funded, it is in effect a "free call option." Our focus is on AGS-003 for renal cancer, which remains on track for interims starting in 2Q and final data mid-'16. We believe 2015 updates on '003 enrollment and data are likely to be a key catalyst for ARGS shares and reiterate our Overweight rating and \$20 price target on Argos.
- **Despite missing endpoint, still signals of efficacy.** Immune response as 2x induction of memory T-cells above baseline, and 3SD above negative control specific responses for HIV antigens, and + for markers of immune function. 70% of 004 patients met criteria for immune response vs. 0% for the negative control arm. Safety was clean, with no SAEs related to drug, and no signs of autoimmunity or adverse lab tests. These data are supportive of the company's plans to go forward with the next Phase IIIs as previously outlined. An adult eradication study looking at 12 patients for treatment with '004 and vorinostat to induce latent virus is ongoing with 5 patients completing the 1st stage. The Phase II pediatric study looking to get those patients off ART is expected to start this year pending protocol approval and funding.

COMPANY DESCRIPTION

Argos Therapeutics develops dendritic cell vaccines for oncology and infectious diseases.

PRICE: US\$9.61

TARGET: US\$20.00

DCF of AGS-003 in metastatic renal cell carcinoma in the U.S. + a technology/pipeline value of ~\$5/share

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RISKS TO ACHIEVEMENT OF PRICE TARGET

Failure of AGS-003 in mRCC Phase III or other studies.

Price Performance - 1 Year



Source: Bloomberg

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