

BIND presents late-breaker clinical data at AACR on BIND-014's promising antitumor effects

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BIND Biosciences, a clinical-stage biopharmaceutical company developing a new class of highly selective targeted therapeutics called Accurins™, announced today the presentation of late-breaker clinical data for BIND-014, the lead drug candidate within a new class of targeted therapeutics that are programmed to concentrate at tumors, at the American Association for Cancer Research (AACR) 2012 Annual Meeting. BIND presented data from the ongoing Phase 1 clinical study of BIND-014, its targeted docetaxel Accurin, in patients with solid tumors that strongly translated from preclinical data, demonstrated safety and tolerability, and showed evidence of anti-tumor activity with six of 17 patients with advanced or metastatic solid tumor cancers. The preliminary Phase 1 data demonstrated partial response or stable disease in this heavily pretreated patient population with durable responses of up to six months in some cases. In addition, BIND-014 demonstrated evidence of anti-tumor activity in tumors for which conventional docetaxel is known to have minimal activity.

BIND-014 represents the first targeted and programmable Accurin [nanomedicine](#) to reach the clinic from BIND's proprietary drug [development platform](#) that creates targeted therapeutics designed to accumulate at the site of disease for high [drug concentration](#) and maximum [therapeutic effect](#). BIND-014 employs a combination of a targeted biodegradable nanoparticle and [docetaxel](#), a proven [cancer](#) drug. The ongoing Phase 1 study has reached a dose of 75 mg/m² with dose

escalation continuing and BIND-014 continues to be well-tolerated in the study.

"The early clinical activity observed with BIND-014 in patients with advanced or metastatic solid tumor cancers is encouraging," commented Daniel D. Von Hoff, M.D., F.A.C.P., Principal Investigator for the study and Physician-in-Chief and Distinguished Professor at the Translational Genomics Research Institute ([TGen](#)) and Chief Scientific Officer for US Oncology and the Scottsdale Clinical Research Institute. "There is a critical need for targeted treatment options for patients with difficult to treat solid tumors and we look forward to further evaluating the potential of BIND-014."

"The emerging BIND-014 clinical data are showing exciting signals of activity, validating the potential for the revolutionary impact of nanomedicines for the treatment of cancer," commented Philip W. Kantoff, MD, Chief Clinical Research Officer, Dana-Farber Cancer Institute, and Professor of Medicine, Harvard Medical School. "What's equally exciting is that I have never witnessed a potentially revolutionary technology go from concept to human clinical testing as rapidly as BIND-014, and this is credit to the world-class team of scientists, engineers, physicians, for-profit and non-profit organizations that have converged to advance this technology."

In a late-breaking poster presentation entitled "A Phase 1, Open Label, Safety, Pharmacokinetic and Pharmacodynamic Dose Escalation Study of BIND-014 Given by IV Infusion to Patients with Advanced or Metastatic Cancer," BIND presented clinical data consistent with preclinical observations in which drug concentration at the tumor site and efficacy in multiple tumor types was demonstrated:

- Preliminary evidence of anti-tumor activity during dose

escalation with evidence of anti-tumor activity in six of the 17 patients treated ranging from one durable confirmed partial response (cervical cancer) and five with stabilization of disease (pancreatic, colorectal, bile duct, tonsillar and anal cancer).

- Evidence of antitumor activity in cancers in which conventional docetaxel has minimal activity.
- At all dose levels studied, with 75 mg/m² reached to date, BIND-014 was generally well-tolerated with no new toxicities observed. Dose escalation continues.
- Strong translation of pharmacokinetic data from preclinical findings to Phase 1 clinical data with highly differentiated PK profile from conventional docetaxel and strong dose linearity across doses. The clinical results are consistent with the preclinical findings that BIND-014 concentrates drug activity in the tumor resulting in improved efficacy.

"We are very pleased with these data as our ongoing clinical study with BIND-014 lays a strong foundation to advance into Phase 2 development later this year. In addition, these data show the emerging potential of BIND-014 to be a significant new cancer therapy for patients by fundamentally changing the pharmacology of docetaxel allowing it to differentially concentrate in the tumors by up to ten-fold, as shown in our preclinical models, for better clinical efficacy across multiple cancers including those in which conventional docetaxel has minimal activity," said Scott Minick, President and Chief Executive Officer of BIND Biosciences. "BIND-014 is the clinical validation of BIND's Accurin technology platform, and marks an important milestone for the field of nanomedicine, BIND and, most importantly, patients."

The Phase 1 study has an ascending, intravenous dose design. The objectives of the study are to determine the safety, tolerability and maximum tolerated dose of BIND-014 and to assess preliminary evidence of antitumor activity. This clinical study is being conducted at

the Virginia G. Piper Cancer Center at Scottsdale Healthcare in Scottsdale, Arizona, in collaboration with the Translational Genomics Research Institute and the Scottsdale Healthcare Research Institute, the Karmanos Cancer Institute in Detroit, Michigan, and Marin Specialty Care in Greenbrae, California.

About BIND-014

BIND-014 is a programmable nanomedicine that combines a targeting ligand and a therapeutic nanoparticle. BIND-014 contains docetaxel, a proven cancer drug which is approved in major cancer indications including breast, prostate and lung, encapsulated in FDA-approved biocompatible and biodegradable polymers. BIND-014 is targeted to prostate specific membrane antigen (PSMA), a cell surface antigen abundantly expressed on the surface of cancer cells and on new blood vessels that feed a wide array of solid tumors. In preclinical cancer models,

BIND-014 was shown to deliver up to ten-fold more docetaxel to tumors than an equivalent dose of conventional docetaxel. The increased accumulation of docetaxel at the site of disease translated to marked improvements in antitumor activity and tolerability. BIND-014 is currently in Phase 1 human clinical testing in cancer patients with advanced or metastatic solid tumor cancers (NCT01300533). The early development of BIND-014 was funded in part by the National Cancer Institute and the U.S. National Institutes of Standards and Technology (NIST) under its Advanced Technology Program (ATP).

Provided by The Yates Network

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