

Publications and Patents

Jason M. Summa

Biotechnology and Pharmaceutical Research

PATENT

Inhalable Epinephrine

Inventors: Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich, Karen Fu, Jeffrey S. Hrkach, Wen-I Li, Michael M. Lipp, Mei-Ling Pan, Jason Summa

Patent Numbers:

WO2004002551A3 (International, filed 2003-06-26)

EP1531794B1 (European)

ES2638987T3 (Spanish)

US Patent 7,947,742 B2

US Patent 8,415,397 B2

US Patent 8,747,813 B2

US20040076588A1

US20170119699A1

US20130253065A1

Assignee: Advanced Inhalation Research, Inc. (later assigned to Alkermes, Inc., then to Corregidor Therapeutics/Civitas Therapeutics)

PEER-REVIEWED PUBLICATIONS

1. Hrkach J, Von Hoff D, Ali MM, Andrianova E, Auer J, Campbell T, De Witt D, Figa M, Figueiredo M, Horhota A, Low S, McDonnell K, Peeke E, Retnarajan B, Sabnis A, Schnipper E, Song JJ, Song YH, Summa J, Tompsett D, Troiano G, Van Geen Hoven T, Wright J, LoRusso P, Kantoff PW, Bander NH, Sweeney C, Farokhzad OC, Langer R, Zale S. Preclinical Development and Clinical Translation of a PSMA-Targeted Docetaxel Nanoparticle with a Differentiated Pharmacological Profile. *Sci Transl Med*. 2012 Mar 7;4(128):128ra39. doi: 10.1126/scitranslmed.3003651.
2. Von Hoff DD, Mita MM, Ramanathan RK, Weiss GJ, Mita AC, LoRusso PM, Burris HA 3rd, Hart LL, Low SC, Parsons DM, Zale SE, Summa JM, Youssoufian H, Sachdev JC. Phase I Study of PSMA-Targeted Docetaxel-Containing Nanoparticle BIND-014 in Patients with Advanced Solid Tumors. *Clin Cancer Res*. 2016 Jul 1;22(13):3157-63. doi: 10.1158/1078-0432.CCR-15-2548. Epub 2016 Feb 4. PMID: 26847057.
3. Autio KA, Dreicer R, Anderson J, Garcia JA, Alva A, Hart LL, Milowsky MI, Posadas EM, Ryan CJ, Graf RP, Dittamore R, Schreiber NA, Summa JM,

Youssoufian H, Morris MJ, Scher HI. Safety and Efficacy of BIND-014, a Docetaxel Nanoparticle Targeting Prostate-Specific Membrane Antigen for Patients With Metastatic Castration-Resistant Prostate Cancer: A Phase 2 Clinical Trial. *JAMA Oncol.* 2018 Oct 1;4(10):1344-1351. doi: 10.1001/jamaoncol.2018.2168. PMID: 29978216; PMCID: PMC6233779.

CONFERENCE ABSTRACTS & PRESENTATIONS

AACR (American Association for Cancer Research)

4. **Von Hoff DD, Mita M, Eisenberg P, LoRusso P, Weiss G, Sachdev J, Mita A, Low S, Hrkach J, Summa J, Berk G, Ramanathan R.** Abstract LB-203: A phase I study of BIND-014, a PSMA-targeted nanoparticle containing docetaxel, in patients with refractory solid tumors. *Cancer Res.* 2013 Apr 15;73(8 Supplement):LB-203. doi: 10.1158/1538-7445.AM2013-LB-203.
5. **Low S, Von Hoff D, Mita M, Burris H, Eisenberg P, Hart L, LoRusso P, Weiss G, Sachdev J, Mita A, Ramanathan R, Hrkach J, Summa J, Berk G.** Abstract 911: Prostate-specific membrane antigen (PSMA) expression as a potential patient selection marker in patients with refractory solid tumors administered BIND-014, a PSMA-targeted nanoparticle containing docetaxel. *Cancer Res.* 2014 Oct 1;74(19 Supplement):911. doi: 10.1158/1538-7445.AM2014-911.
6. **Summa J, Von Hoff D, Sachdev J, Mita M, LoRusso P, Eisenberg P, Burris H, Hart L, Youssoufian H, Parsons D, Low S.** Abstract 5514: Pharmacokinetics of BIND-014 (docetaxel nanoparticles for injectable suspension) in preclinical species and patients with advanced solid tumors. *Cancer Res.* 2015 Aug 1;75(15 Supplement):5514. doi: 10.1158/1538-7445.AM2015-5514.

AACR-NCI-EORTC Molecular Cancer Therapeutics

7. **Summa JM, Von Hoff DD, Sachdev JC, Mita MM, LoRusso PM, Eisenberg PD, Burris HA, Hart LL, Youssoufian H, Parsons DM, Low SC.** Abstract B144: Evaluation of total and encapsulated drug pharmacokinetics for BIND-014 (docetaxel nanoparticles for injectable suspension) in a phase 1 study. *Mol Cancer Ther.* 2015 Dec;14(12 Supplement 2):B144. doi: 10.1158/1535-7163.TARG-15-B144.
8. **Summa J, Kung J, Adams LK, Zale SE, Youssoufian H.** Abstract A161: Cardiovascular safety profile of BIND-014 (docetaxel nanoparticles for injectable suspension) evaluated in phase 1 and 2 studies. *Mol Cancer Ther.* 2015 Dec;14(12 Supplement 2):A161. doi: 10.1158/1535-7163.TARG-15-A161.

ASCO (American Society of Clinical Oncology)

9. **Autio KA, Garcia JA, Alva AS, Hart LL, Milowsky MI, Posadas EM, Ryan CJ, Summa JM, Youssoufian H, Scher HI, Dreicer R.** A phase 2 study of BIND-014 (PSMA-targeted docetaxel nanoparticle) administered to patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC). *J Clin Oncol.* 2016;34(2_suppl):233.

10. **Smith MR, Sandhu SK, Kelly WK, Scher HI, Efstathiou E, Lara P, Yu EY, George DJ, Chi KN, Summa J, Kothari N, Zhao X, Espina BM, Ricci DS, Simon JS, Tran N, Fizazi K, GALAHAD Investigators.** Phase II study of niraparib in patients with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD): Preliminary results of GALAHAD. *J Clin Oncol.* 2019;37(7_suppl):202.
11. **Smith MR, Fizazi K, Sandhu SK, Kelly WK, Efstathiou E, Lara P, Yu EY, George DJ, Chi KN, Saad F, Summa J, Freedman JM, Mason GE, Zhu E, Ricci DS, Simon JS, Cheng S, Fizazi K.** Niraparib in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD): Correlative measures of tumor response in phase II GALAHAD study. *J Clin Oncol.* 2020;38(6_suppl):118.

ESMO (European Society of Medical Oncology)

12. **Smith MR, Sandhu SK, Kelly WK, Scher HI, Efstathiou E, Lara P, Yu EY, George DJ, Chi KN, Summa J, et al.** Pre-specified interim analysis of GALAHAD: A phase II study of niraparib in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD). *Ann Oncol.* 2019;30(Suppl 5):v884–v885. [ESMO Congress Abstract LBA50, Barcelona, Spain, September 2019]

SUMMARY

Total Publications: 13 (3 peer-reviewed articles + 9 conference abstracts + 1 additional presentation reference)

Patents: 1 (with multiple jurisdictional filings)