

## CURRICULUM VITAE

### Bo H Chao, MD, MS

#### SUMMARY

Dr. Chao is a board-certified medical oncologist (sub-specialty in thoracic oncology) and has been a drug developer since 2010 when he designed and wrote his first clinical study protocol at the University of Wisconsin Carbone Cancer Center. Dr. Chao was a Principal Investigator for 20 clinical studies at The Ohio State University James Cancer Hospital before he joined Eli Lilly and Company in 2015. He has led the development strategy of various treatments for cancer; led and managed Phase I, II, and III clinical studies; served as the medical lead for regulatory submissions (including Investigational New Drug Applications, Biologics License Applications, New Drug Applications, and Market Authorization Applications) of Cyramza® (ramucirumab), Tyvyt® (sintilimab), Retevmo® (selpercatinib), and alisertib (MLN8237); published as the first author or a senior author in various peer-reviewed research journals; and represented the company as the lead for lung cancer and breast cancer drug development in external engagement.

Dr. Chao earned his Doctor of Medicine and Master of Science in Biomedical Engineering dual degrees at the University of Minnesota in Twin Cities. He is also a volunteer professor at Weill Cornell Medical College (Division of Medical Oncology) in New York City.

#### POSITIONS & HIGHLIGHTS

9/2024 – Present

**Consultant for Oncology Clinical Development Strategy** (Independent)

- ~~Working directly with biotech CEO/CSO/CMOs on data interpretation, clinical development strategy, and regulatory strategy in oncology drug development~~

11/2017 – Present

**New York-Presbyterian Weill Cornell Medical College**, New York, NY  
*Clinical Assistant Professor of Medicine (Courtesy), Medical Oncology*

- ~~Voluntary attending physician supervising medical oncology fellows~~

10/2023 – 7/2024

**Puma Biotechnology**, Los Angeles, CA  
*Senior Vice President, Global Clinical Development, Oncology*

- ~~Lead of clinical development for the pipeline of the company, focusing on breast cancer and lung cancer indications of alisertib, working directly with its CEO and Board of Directors~~

2/2015 - 10/2023

**Eli Lilly and Company**, New York, NY  
*Executive Medical Director, Global Clinical Development, Oncology*  
(3/2022 - 10/2023)

- ~~Medical lead representing Lilly leadership, in collaboration with SWOG leadership, Merck leadership, and the FDA leadership, for Pragmatica Lung (phase 3 study of~~

ramucirumab + pembrolizumab in previously treated NSCLC)

- Medical lead for developing lung cancer indications of seliperatinib and ramucirumab

Senior Medical Director, Global Clinical Development, Oncology (10/2017 - 2/2022)

- Medical lead representing Lilly leadership in collaboration with SWOG/Lung MAP for various collaborative studies involving ramucirumab
- Medical lead obtaining IND approval by the FDA for seliperatinib
- Medical lead for BLA submission and ODAC preparation of sintilimab
- Medical lead for developing lung cancer indications of seliperatinib, ramucirumab, sintilimab, and pegilodecakin
- Q4 2020 Lilly Innovator Award

Medical Director, Global Clinical Development, Oncology (2/2015 - 9/2017)

- Medical lead obtaining MAA approval by the EMA for ramucirumab
- Medical lead for developing lung cancer indications of ramucirumab

8/2012 – 1/2015

The Ohio State University, Columbus, OH

Assistant Professor, Department of Medicine, Division of Medical Oncology

- Institutional Principal Investigator for 20 clinical studies focused on lung cancer, including phase 1, 2, and 3

7/2011 – 6/2012

University of Wisconsin, Madison, WI

Clinical Instructor, Department of Medicine, Division of Hematology and Oncology

- NIH NRS4 T32 physician scientist trainee

### EXTERNAL ADVISORY BOARD

#### **US NCI Cooperative Group**

2020 – 2023 Southwest Oncology Group (SWOG) Lung-MAP Company Advisory Board Member Development strategy of novel regimens in stage IV NSCLC; representing Eli Lilly

### SELECTED REGULATORY SUBMISSIONS

#### **Medical Lead**

Investigational New Drug Application      Seliperatinib (2021)  
Alisertib plus endocrine therapy of choice (2024)

Biologics License Application      Sintilimab (2021)

Marketing Authorization Application      Ramucirumab (2015)

### UNITED STATES PATENT APPROVAL

## **Inventor**

US-11471457-B2 (2022)

Method of treating epithelial growth factor receptor (EGFR) T790M-positive non-small cell lung cancer by administering a combination of a VEGFR-2 antibody and osimertinib

## **SELECTED CLINICAL STUDIES & HIGHLIGHTS**

### **Phase 1 Studies**

- ~~Led concept, design, implementation, and publication of primary outcome: I4T MC JVDF (NCT02443324), I4T MC JVDF (NCT02789345).~~
- ~~Principal Investigator: NP28761 (NCT01871805), AP26113-11-101 (NCT01449461), 200858 (NCT02034123), CO-1686-008 (NCT01526928).~~

### **Phase 2 Studies**

- ~~Led concept, design, and implementation including IND approval: J2G-0X JZJA (NCT03157128), PUMA-ALI-1201 (NCT06369285).~~
- ~~Led design, implementation, and publication of primary outcome: J1L-AM JZGC (NCT03382899), J1L-AM JZGD (NCT03382912).~~
- ~~Led design and implementation: PUMA-ALI-1201 (NCT06095505).~~
- ~~Led concept and design: Lung-MAP-S1800A (NCT03971474).~~

### **Phase 3 Studies**

- ~~Led concept, design, and implementation including IND approval: LIBRETTO-432 (NCT04819100; selipareatinib).~~
- ~~Led concept and design: Pragmatica-Lung (NCT05633602; ramucirumab and pembrolizumab), LIBRETTO-431 (NCT04194944; selipareatinib).~~
- ~~Led regulatory submissions after primary readout: REVEL (NCT01168973; ramucirumab; M44/EM4), ORIENT-11 (NCT03607539; sintilimab; BLA/FDA).~~

## **EDUCATION**

### **Undergraduate:**

6/1995 – 8/1996      Chemical Engineering  
Auburn University, Auburn, AL

9/1996 – 6/1999      Bachelor of Chemical Engineering, *Magna Cum Laude*  
Minors in Chemistry and Biology  
University of Minnesota, Twin Cities, MN

### **Graduate:**

6/2001 – 6/2003      Master of Science in Biomedical Engineering  
Minor in Mechanical Engineering  
University of Minnesota, Twin Cities, MN

7/1999 – 5/2005      Doctor of Medicine  
University of Minnesota Medical School, Minneapolis, MN

### **Post Graduate Training:**

7/2005 – 6/2006	Internship, Internal Medicine Virginia Commonwealth University Health System, Richmond, VA
7/2006 – 6/2008	Residency, Internal Medicine Virginia Commonwealth University Health System, Richmond, VA
7/2009 – 6/2011	Clinical Fellowship, Medical Oncology University of Wisconsin Hospital and Clinics, Madison, WI
7/2010 – 6/2012	NIH NRSA T32 Postdoctoral Trainee, Biomedical Engineering/Oncology University of Wisconsin Carbone Cancer Center, Madison, WI

### **CERTIFICATIONS**

ABIM Board Certified in Internal Medicine, 2008 – 2022

ABIM Board Certified in Medical Oncology, 2011 – Present

### **LICENSURE**

Commonwealth of Virginia Medical License, 2008 – 2010 (Expired)

State of Wisconsin Medical License, 2009 – 2013 (Expired)

State of Ohio Medical License, 2012 – 2019 (Expired)

State of New York Medical License, 2017 – 2026 (Active)

### **SOCIETY MEMBERSHIPS**

2009 – Present American Society of Clinical Oncology  
 2009 – Present American Association for Cancer Research  
 2013 – Present International Association for the Study of Lung Cancer  
 2014 – 2015 Southwest Oncology Group

### **PUBLICATIONS**

- *Chao BH, He X, Bischof JC. Pre-treatment inflammation induced by TNF alpha augments cryosurgical injury on human prostate cancer. Cryobiology 2004;49:10-27. <https://doi.org/10.1016/j.cryobiol.2004.04.005>*
- *Chao BH, Cline Parhamovich K, Grizzard JD, Smith TJ. Fatal Loeffler's endocarditis due to hyper eosinophilic syndrome. Am J Hematol 2007;82:920-923. <https://doi.org/10.1002/ajh.20933>*
- *Chao BH, Stogner Underwood KA, Kiev J, Smith TJ. Intrathoracic malignant peripheral nerve sheath tumor in neurofibromatosis 1. J Clin Oncol 2008;26:2216-2218. <https://doi.org/10.1200/jco.2007.14.6753>*
- *Chao BH, Kidd JM, Dow AW. Methicillin-resistant Staphylococcus aureus bacteremia due to prostatic abscess. J Hosp Med 2009;4:E9-E11. <https://doi.org/10.1002/jhm.379>*

- Hauck P, Chao BH, Litz J, Krystal GW. Alterations in the Noxa/Mcl-1 axis determine sensitivity of small cell lung cancer to the BH3 mimetic ABT-737. Mol Cancer Ther 2009;8:883-892. <https://doi.org/10.1158/1535-7163.mct-08-1118>
- Chao BH, Lepeak L, Leal T, Robins HH. Clinical use of the low molecular weight heparins in cancer patients: Focus on the improved patient outcomes. Thrombosis 2011; vol. 2011, Article ID 530183, 10 pages. doi:10.1155/2011/530183. PMCID: PMC3195390. <https://doi.org/10.1155/2011/530183>
- Liu G, Jeraj R, Vanderhoek M, Perlman S, Kolesar J, Harrison M, Simone U, Eickhoff J, Carmichael L, Chao B, Marnocha R, Ivy P, Wilding G. Pharmacodynamic study using FLT PET/CT in patients with renal cell cancer and other solid malignancies treated with sunitinib malate. Clin Cancer Res 2011;17:7634-44. PMCID: 3243764. <https://doi.org/10.1158/1078-0432.ccr-11-1677>
- Chao BH, Briesewitz R, Villalona-Calero MA. RET fusion genes in non-small cell lung cancer. J Clin Oncol 2012;30(35):4439-41. PMID: 23150705. <https://doi.org/10.1200/jco.2012.45.8240>
- Shaw AT, Gandhi L, Gadgeel S, Riely GJ, Cetnar J, West H, Camidge DR, Socinski MA, Chiappori A, Mekhail T, Chao BH, Borghaei H, Gold KA, Zeaiter A, Bordogna W, Balas B, Puig O, Henschel V, Ou S-H. Alectinib in ALK positive, crizotinib-resistant, non-small cell lung cancer: a single-group, multicentre, phase 2 trial. Lancet Oncol 2016;17(2):234-42. PMCID: PMC4752892. [https://doi.org/10.1016/s1470-2045\(15\)00488-8](https://doi.org/10.1016/s1470-2045(15)00488-8)
- Villalona-Calero MA, Lam E, Otterson GA, Zhao W, Timmons M, Subramaniam D, Hade EM, Gill GM, Coffey M, Selvaggi G, Bertino E, Chao B, Knopp MV. Oncolytic reovirus in combination with chemotherapy in metastatic or recurrent non-small cell lung cancer patients with KRAS-activated tumors. Cancer 2016;122(6):875-83. PMID: 26709987. <https://doi.org/10.1002/ener.29856>
- Siegele BJ, Shilo K, Chao BH, Carbone DR, Zhao W, Ioffe O, Franklin WA, Edelman MJ, Aisner DL. Epidermal growth factor receptor (EGFR) mutations in small cell lung cancers: Two cases and a review of the literature. Lung Cancer 2016;95:65-72. PMID: 27040854. <https://doi.org/10.1016/j.lungcan.2016.02.012>
- Spigel DR, Chaft JE, Gettinger S, Chao BH, Dirix L, Schmid P, Chow LQM, Hicks RJ, Leon L, Fredrickson J, Kowanetz M, Sandler A, Funke R, Rizvi NA. FIR: Efficacy, Safety, and Biomarker Analysis of a Phase II Open-Label Study of Atezolizumab in PD-L1-Selected Patients with Non-Small-Cell Lung Cancer. J Thorac Oncol 2018;13(11):1733-1742. PMID: 29775807. <https://doi.org/10.1016/j.jtho.2018.05.004>
- Yu HA, Paz-Ares LG, Yang JCH, Lee KH, Garrido P, Park K, Kim JH, Lee DH, Mao H, Wijayawardana SR, Gao L, Hozak RR, Chao BH, Planchard D. Phase I Study of the Efficacy and Safety of Ramucicirumab in Combination with Osimertinib in Advanced T790M-Positive EGFR-Mutant Non-Small-Cell Lung Cancer. Clin Cancer Res 2021 Feb 15;27(4):992-1002. PMID: 33046516. <https://doi.org/10.1158/1078-0432.ccr-20-1690>
- Herbst RS, Arkenau HT, Bendell J, Arrowsmith E, Wernke M, Soriano A, Penel N, Santana-Davila R, Bischoff H, Chau I, Mi G, Wang H, Rasmussen E, Ferry D, Chao BH,

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Paz-Ares L. Phase 1 Expansion Cohort of Ramucirumab Plus Pembrolizumab in Advanced Treatment Naïve NSCLC. J Thorac Oncol 2021 Feb;16(2):289-298. PMID: 33068794. <https://doi.org/10.1016/j.jtho.2020.10.004>

- Spigel D, Jotte R, Nemunaitis J, Shum M, Schneider J, Goldschmidt J, Eisenstein J, Berg D, Seneviratne L, Socoteanu M, Bhandari V, Konduri K, Xia M, Wang H, Hozak R, Gueorguieva I, Ferry D, Gandhi L, Chao BH, Rybkin I. Randomized Phase 2 Studies of Checkpoint Inhibitors Alone or in Combination with Pegilodecakin in Patients with Metastatic NSCLC (CYPRESS 1 and CYPRESS 2). J Thorac Oncol 2021 Feb;16(2):327-333. PMID: 33166722. <https://doi.org/10.1016/j.jtho.2020.10.001>
- Tsuboi M, Goldman JW, Wu Y-L, Johnson ML, Paz Ares L, Yang J-C H, Besse B, Su W, Chao BH, Drilon A. LIBRETTO 432, a phase III study of adjuvant selipareatinib or placebo in stage IB-III A RET fusion positive non-small-cell lung cancer. Future Oncol 2022 Sep;18(28):3133-3141. PMID: 35950566. <https://doi.org/10.2217/fon-2022-0656>
- Goldman JW, Sholl LM, Dacic S, Fishbein MC, Mureiano-Goroff YR, Rajaram R, Szymezak S, Szpurka AM, Chao BH, Drilon A. Case Report: Complete Pathological Response to Neoadjuvant Selipareatinib in a Patient with Resectable Early Stage RET Fusion Positive Non-Small Cell Lung Cancer. Front Oncol 2023 May 18;13:1178313. PMID: 37274265. <https://doi.org/10.3389/fonc.2023.1178313>

## CHAPTERS

- Chao BH, Robins HI. The use of low molecular weight heparin in the treatment and prevention of thromboembolic disease in glioma patients. Tumors of the Central Nervous System Ed. Hayat MA. Springer, New York, NY, 2011

## ABSTRACTS

- Hauck PM, Chao BH, Litz J, Krystal GW. NOXA expression determines the sensitivity of small cell lung cancer to ABT 737. In: Proceedings of the 99<sup>th</sup> Annual Meeting of the American Association for Cancer Research; 2008 Apr 12-16; San Diego, CA. Philadelphia (PA): AACR; 2008. Abstract 4380
- Chao BH, LoConte NK, Schelman WR, Mulkerin D, Huie MS, Eickhoff JC, Holen KD. A phase II study of neoadjuvant FOLFOX4 and cetuximab (C) in patients with locally advanced rectal adenocarcinoma (RA). 2010 ASCO Annual Meeting, Chicago, IL, June 2010. Abstract e14122
- Chao BH, Harrison MR, Kolesar J, Vanderhock M, Perlman S, Eickhoff JC, Carmichael L, Alberti DB, Wilding G, Jeraj R, Liu G. Pharmacodynamic and pharmacokinetic characterization of tumor proliferation during acute sunitinib (SU) withdrawal. 2011 ASCO Annual Meeting, Chicago, IL, June 2011. Abstract e13556
- Chao BH, Sung KE, Yin J, Beebe DJ. The inhibitory effect of tumor microenvironment on oncolytic virotherapy in lung cancer [abstract]. In: Proceedings of the AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics; 2011 Nov 12-16; San Francisco, CA. Philadelphia (PA): AACR; Mol Cancer Ther 2011;10(11 Suppl): Abstract nr C236

- Chao BH, Traynor AM, Yang DT, Zhang C, Pier T, Kim K, Rehrauer WM, Cannon DM, Cannon GM, Bye T, Tibbetts RS. Automated quantitative analyses (AQUA) of cyclin-AMP response element binding protein (CREB), phosphorylated CREB (pCREB), and ataxia telangiectasia mutated protein kinase (ATM) protein expression in patients undergoing thoracic radiation for locally advanced non-small cell lung cancer (NSCLC). 2012 ASCO Annual Meeting, Chicago, IL, June 2012. Abstract e13537
- Villalona-Calero M, Lam E, Zhao W, Otterson G, Subramaniam D, Chao BH, Timmons M, Schaaf L, Gill GM, Coffey M. Final Results of a Phase 2 Trial of the Oncolytic Virus Reovirus Serotype 3 Dearing Strain (REOLYSIN®) in Metastatic NSCLC Patients with a Ras-activated Pathway. 15<sup>th</sup> World Conference on Lung Cancer, 2013 Oct 27-30; Sydney, Australia. J Thorac Oncol 2013;8(2 Suppl): Abstract P1.11-026
- Besse B, Soria J-C, Yao B, Kris M, Chao B, Cortot A, Mazieres J, Socinski MA, Horn L, Waqar S, Barlesi F, Gray JE, Moro-Sibilot D, Oton A, Quoix E, Lalani AS, McCulloch L, Bryce R, Gandhi L. Neratinib with or without temsirolimus in patients with non-small cell lung cancer carrying HER2 somatic mutations: An international randomized phase II study. European Society for Medical Oncology Congress; 2014 Sept 26-30; Madrid, Spain. Abstract LB439-PR
- Soria J-C, Sequist LV, Goldman JW, Wakelee HA, Gadgeel SM, Varga A, Yu HA, Solomon BJ, Ou S-H, Papadimitrakopoulou V, Oxnard GR, Horn L, Dziadziuszko R, Chao B, Spira AI, Liu S, Mekhail T, Matheny S, Litten J, Camidge R. Interim phase 2 results of study CO-1686-008: A phase 1/2 study of the irreversible, mutant selective, EGFR inhibitor rociletinib (CO-1686) in patients with advanced non-small cell lung cancer. 26<sup>th</sup> EORTC NCI AACR Symposium on Molecular Targets and Cancer Therapeutics; 2014 Nov 18-21; Barcelona, Spain. Abstract 10LB4
- Gandhi L, Shaw A, Gadgeel SM, Riely G, Cetnar J, West HJ, Camidge DR, Socinski MA, Chiappori A, Mekhail T, Chao BH, Borghaei H, Gold KA, Zeaiter AH, Bordogna W, Balas B, Puig O, Henschel V, Ou S-H. A phase II, open-label, multicenter study of the ALK inhibitor alectinib in an ALK+ non-small cell lung cancer (NSCLC) US/Canadian population who had progressed on erizotinib (NP28761). ASCO Annual Meeting; 2015 May 29-June 2; Chicago, IL. J Clin Oncol 33:5s, 2015 (suppl; abstr 8019).
- Spigel DR, Chaft JE, Gettinger SN, Chao BH, Dirix LY, Schmid P, Chow LQM, Chappey C, Kowanetz M, Sandler A, Funke RP, Rizvi NA. Clinical activity and safety from a phase II study (FIR) of MPDL3280A (anti-PDL1) in PD-L1-selected patients with non-small cell lung cancer (NSCLC). ASCO Annual Meeting; 2015 May 29-June 2; Chicago, IL. J Clin Oncol 33:5s, 2015 (suppl; abstr 8028).
- Sequist LV, Goldman JW, Wakelee HA, Camidge DR, Yu HA, Varga A, Solomon B, Oxnard GR, Ou S-H, Papadimitrakopoulou V, Chao BH, Liu S, Reckamp KL, Spira AI, Piotrowska Z, Despain D, Karlovich CA, Yurasov S, Soria J-C. Efficacy of rociletinib (CO-1686) in plasma-genotyped T790M-positive non-small cell lung cancer (NSCLC) patients (pts). ASCO Annual Meeting; 2015 May 29-June 2; Chicago, IL. J Clin Oncol 33:5s, 2015 (suppl; abstr 8001).
- Villalona M, Lam E, Otterson G, Zhao W, Timmons M, Subramaniam D, Hade E,

- Bertino E, Chao B, Selvaggi G, Knopp M, Gill GM. Oncolytic reovirus in combination with paclitaxel/carboplatin in NSCLC patients with Ras activated malignancies, long term results. IASLC 16th World Conference on Lung Cancer; 2015 September 6-9; Denver, CO. Abstract MIN130.01
- Chaft J, Chao B, Akerly W, Gordon MS, Antonia SJ, Callahan J, Sandler A, Funke R, Leon L, Fredrickson J, Kowanetz M, Gettinger S. Evaluation of PD-L1 expression in metachronous tumor samples and FDG-PET as a predictive biomarker in Ph2 study (FIR) of atezolizumab (MPDL3280A). IASLC 16<sup>th</sup> World Conference on Lung Cancer; 2015 September 6-9; Denver, CO. Abstract ORAL02.06
  - Shaw A, West H, Socinski MA, Ou I, Gandhi L, Gadgeel S, Belani CP, Shirai K, Bazhenova L, Santos E, Riely GJ, Chiappori A, Cetnar J, Mekhail T, Chao B, Borghaei H, Gold KA, Johannsdottir H, Ruf T, Boissierie F, Henshel V, Zeaiter A, Camidge R. Updated efficacy/safety data from the phase 2 NP28761 study of alectinib in ALK+ NSCLC. IASLC 16<sup>th</sup> World Conference on Lung Cancer; 2015 September 6-9; Denver, CO. Abstract ORAL33.03
  - Puig O, Yang JCH, Ou SHI, Chiappori A, Chao BH, Belani CP, Spira A, Bearz A, Duruisseaux M, Allard J, Birzele F, Boissierie F, Lonngren U, Bordogna W, Klass D, Newman AM, Zeaiter A, Shaw AT. Pooled mutation analysis for the NP28673 and NP28761 studies of alectinib in ALK+ non-small cell lung cancer (NSCLC). ASCO Annual Meeting; 2016 June 3-7; Chicago, IL. Abstract 9061
  - Planchard D, Kris MG, Besse B, Hozak RR, He S, Gan F, Wolff K, Chao BH, Yu H. Phase 1 Study of Ramucirumab or Necitumumab in Combination with Osimertinib (AZD9291) in Advanced T790M Positive EGFR Mutant NSCLC. IASLC 17<sup>th</sup> World Conference on Lung Cancer; 2016 December 4-7; Vienna, Austria. Abstract P2.06-005
  - Camidge DR, Gadgeel SM, Ou SI, Gandhi L, Riely GJ, Cetnar J, West H, Socinski MA, Chiappori A, Mekhail TM, Chao BH, Borghaei H, Gold KA, Bordogna W, Balas B, Noe J, Golding S, Zeaiter A, Shaw A. Updated Efficacy and Safety Data from the Phase 2 NP28761 Study of Alectinib in ALK Positive Non-Small Cell Lung Cancer. IASLC 17<sup>th</sup> World Conference on Lung Cancer; 2016 December 4-7; Vienna, Austria. Abstract MA07.02
  - Yu H, Planchard D, Yang JCH, Lee KH, Garrido P, Park K, Kim JH, Lee DH, He S, Wolff K, Chao BH, Paz-Ares L. Osimertinib with Ramucirumab or Necitumumab in Advanced T790M positive EGFR Mutant NSCLC: Preliminary Ph1 Study Results. IASLC 18<sup>th</sup> World Conference on Lung Cancer; 2017 October 15-18; Yokohama, Japan. Abstract P1.04-7940
  - Planchard D, Yu H, Yang JCH, Lee KH, Garrido P, Park K, Kim JH, Lee DH, Mao H, Chao BH, Paz-Ares L. Efficacy and Safety Results of Ramucirumab in Combination with Osimertinib in Advanced T790M positive EGFR mutant NSCLC. ASCO Annual Meeting; 2018 June 1-5; Chicago, IL. Abstract 9053
  - Paz-Ares L, Planchard D, Yang JCH, Lee KH, Garrido P, Park K, Kim JH, Lee DH, Mao



H, Chao BH, Yu H. CNS Activity of Ramucirumab in Combination with Osimertinib in Patients with Advanced T790M Positive EGFR Mutant NSCLC. IASLC 19<sup>th</sup> World Conference on Lung Cancer; 2018 September 23-26; Toronto, Canada. Abstract MA26-12295

- Herbst RS, Arkenau HT, Bendell J, Arrowsmith E, Wermke M, Soriano A, Penel N, Santana-Davila R, Bischoff H, Chau I, Chao BH, Ferry D, Mi G, Paz Ares Rodriguez L. Phase I expansion cohort of ramucirumab plus pembrolizumab in advanced treatment naïve non-small cell lung cancer (JVDF). IASLC 20<sup>th</sup> World Conference on Lung Cancer; 2019 September 7-10; Barcelona, Spain. Abstract MA14-209
- Jotte RM, Goldschmidt JH, Schneider JG, Shum MK, Berz D, Seneviratne LC, Socoteanu MP, Hung A, Hozak RR, Chao BH, Nemunaitis JJ. Randomized phase II study of nivolumab (N) alone versus with pegilodecakin (PEG) in combination with N in patients (pts) with post platinum immunotherapy naïve stage IV non-small cell lung cancer (NSCLC) and no or low PD-L1 expression (CYPRESS 2). 2020 ASCO Virtual Scientific Program. J Clin Oncol 38: 2020 (suppl; abstr e21744).
- Spigel DR, Shum MK, Schneider JG, Jotte RM, Eisenstein JL, Bhandari VK, Konduri K, Hung A, Hozak RR, Ferry DR, Gandhi L, Chao BH, Rybkin H. Randomized phase II study of pembrolizumab (P) alone versus pegilodecakin (PEG) in combination with P as first line (1L) therapy in patients (pts) with stage IV non-small cell lung cancer (NSCLC) with high PD-L1 expression (CYPRESS 1). 2020 ASCO Virtual Scientific Program. J Clin Oncol 38: 2020 (suppl; abstr 9563).
- Goldman J, Besse B, Wu YL, Yang JCH, Paz Ares L, Drilon A, Johnson M, Xia M, Chao BH, Tsuboi M. LIBRETTO-432: A placebo-controlled Phase 3 study of adjuvant selpercatinib in Stage IB-III A RET fusion-positive NSCLC. IASLC 2021 World Conference on Lung Cancer Worldwide Virtual Event. J Thorac Oncol 16 (10): 2021 (suppl; S975-S976, abstr P01.01).
- Rajaram R, Sholl L, Dacic S, Goldman J, Tan DSW, Gautschi O, Loong HHH, de Braud F, Massarelli E, Levy B, Dy GK, Kang S, Szymezak S, Chao BH, Drilon A. LIBRETTO-001 cohort 7: A single-arm phase 2 study of neoadjuvant selpercatinib in patients with resectable stage IB-III A RET fusion-positive NSCLC. 2022 ASCO Annual Meeting. Chicago, IL. Abstract TPS8594

## CLINICAL STUDIES

### Industry-Sponsored Clinical Studies:

- |           |  |
|-----------|--|
| 2013–2014 | NP28761 (NCT01871805)<br>Title: A Phase I/II Study of the ALK Inhibitor CH5424802 in Patients with ALK-Rearranged Non-Small Cell Lung Cancer<br>Institutional Principal Investigator: Bo H Chao, MD  |
| 2013–2014 | PUMA-NER-4201 (NCT01827267)<br>Title: A Phase 2 Study of Neratinib and Neratinib Plus Temsirolimus in Patients with Non-Small Cell Lung Cancer Carrying Known HER2 Activating Mutations<br>Institutional Principal Investigator: Bo H Chao, MD |

- 2013–2014 GO28625 (NCT01846416)  
Title: A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with PD-L1-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer (FIR)  
Institutional Principal Investigator: Bo H Chao, MD
- 2014 CLDK378A2303 (NCT01828112)  
Title: A Phase III, Multicenter, Randomized, Open-Label Study of Oral LDK378 versus Standard Chemotherapy in Adult Patients with ALK-Rearranged (ALK-Positive) Advanced Non-Small Cell Lung Cancer Who Have Been Treated Previously with Chemotherapy (Platinum Doublet) and Crizotinib  
Institutional Principal Investigator: Bo H Chao, MD
- 2014 1199.93 (NCT01907100)  
Title: Double Blind, Randomised, Multicentre, Phase II Study of Nintedanib in Combination with Pemetrexed / Cisplatin Followed by Continuing Nintedanib Monotherapy versus Placebo in Combination with Pemetrexed / Cisplatin Followed by Continuing Placebo Monotherapy for the Treatment of Patients with Unresectable Malignant Pleural Mesothelioma  
Institutional Principal Investigator: Bo H Chao, MD
- 2014 AP26113-11-101 (NCT01449461)  
Title: A Phase 1/2 Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-Tumor Activity of the Oral ALK/EGFR Inhibitor AP26113  
Institutional Principal Investigator: Bo H Chao, MD
- 2014–2015 200858 (NCT02034123)  
Title: A Phase I Open-Label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK2879552 Given Orally in Subjects with Relapsed/Refractory Small Cell Lung Carcinoma  
Institutional Principal Investigator: Bo H Chao, MD
- 2014–2015 CO-1686-008 (NCT01526928)  
Title: A Phase 1/2, Open-Label, Safety, Pharmacokinetic and Preliminary Efficacy Study of Oral CO-1686 in Patients with Previously Treated Mutant EGFR Non-Small Cell Lung Cancer (NSCLC)  
Institutional Principal Investigator: Bo H Chao, MD
- 2014–2015 CA209-026 (NCT02041533)  
Title: An Open-Label, Randomized, Phase 3 Trial of Nivolumab versus Investigator's Choice Chemotherapy as First-Line Therapy for Stage IV or Recurrent PD-L1+ Non-Small Cell Lung Cancer (CheckMate 026)  
Institutional Principal Investigator: Bo H Chao, MD
- 2016–2021 I4T-MC-JVDL (NCT02789345)  
Title: An Open-Label, Multicenter, Phase 1 Study with Expansion Cohorts of Ramucirumab or Necitumumab in Combination with Osimertinib in Patients with Advanced T790M-Positive EGFR-Mutant Non-Small Cell Lung Cancer after Progression on First-Line EGFR TKI Therapy  
Medical Director: Bo H Chao, MD
- 2019–2023 I4T-MC-JVCY (NCT02411448)

Title: A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination With Ramucirumab or Placebo in Previously Untreated Patients With EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer  
Medical Director: Bo H Chao, MD

2019–2020 J1L-AM-JZGD (NCT03382912)  
Title: A Randomized Phase 2 Trial of AM0010 in Combination With Nivolumab vs. Nivolumab Alone as Second-Line Therapy in Subjects With Stage IV / Metastatic Wild Type Non-Small Cell Lung Cancer and Low Tumor Expression of PD-L1  
Medical Director: Bo H Chao, MD

2019–2020 J1L-AM-JZGC (NCT03382899)  
Title: A Randomized Phase 2 Trial of AM0010 in Combination With Pembrolizumab vs. Pembrolizumab Alone as First-Line (1L) Therapy in Patients With Stage IV / Metastatic Wild Type (WT) Non-Small Cell Lung Cancer and Tumors With High Expression of PD-L1 (> 50%)  
Medical Director: Bo H Chao, MD

2021–2022 J2G-OX-JZJA (NCT03157128)  
Title: A Study of Oral LOXO-292 in Patients With Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors With RET Activation (LIBRETTO-001); Cohort 7  
Medical Director: Bo H Chao, MD

2021–2023 J2G-MC-JZJX (NCT04819100)  
Title: LIBRETTO-432: A Placebo-controlled Double-Blinded Randomized Phase 3 Study of Adjuvant Selpercatinib Following Definitive Locoregional Treatment in Participants With Stage IB-III A RET Fusion-Positive NSCLC  
Medical Director: Bo H Chao, MD

2023–2024 PUMA-ALI-4201 (NCT06095505)  
Title: A Study of Alisertib in Patients With Extensive Stage Small Cell Lung Cancer (ALISCA-Lung1)  
Medical Lead: Bo H Chao, MD

2024–2024 PUMA-ALI-1201 (NCT06369285)  
Title: A Study of Alisertib in Combination With Endocrine Therapy in Patients With HR-positive, HER2-negative Recurrent or Metastatic Breast Cancer (ALISCA-Breast1)  
Medical Lead: Bo H Chao, MD

#### **Investigator-Initiated Clinical Studies:**

2012–2013 REO 016 (NCT00861627)  
Title: Phase 2 Study of REOLYSIN® in Combination With Paclitaxel and Carboplatin for Non-Small Cell Lung Cancer With KRAS or EGFR Activation  
Principal Investigator: Miguel A Villalona, MD  
Co-Investigator: Bo H Chao, MD

2012–2013 NCI-2011-03631 (NCT01468896)  
Title: Cetuximab and Interleukin-12 in Treating Patients With Head and Neck Cancer That is Recurrent, Metastatic, or Cannot Be Removed By Surgery

Principal Investigator: William E Carson III, MD  
Co-Investigator: Bo H Chao, MD

2012–2013    NCI-2009-01606 (NCT01064921)  
Title: Phase I Vorinostat in the Treatment of Advanced Staged Oropharyngeal Squamous Cell Carcinoma  
Principal Investigator: Theodoros Teknos, MD  
Co-Investigator: Bo H Chao, MD

2014            13-103 (NCT01813734)  
Title: A Phase II, Open-Label Study of Ponatinib, A Multi-targeted Oral Tyrosine Kinase Inhibitor, in Advanced Non-Small Cell Lung Cancer Harboring RET Translocations  
Principal Investigator: Alice Shaw, MD (Massachusetts General Hospital)  
Co-Investigator: Bo H Chao, MD

**NCI-Sponsored Cooperative Group Studies:**

2012–2013    E 1505  
Title: Chemotherapy With or Without Bevacizumab in Treating Patients With Stage IB, Stage II, or Stage IIIA Non-Small Lung Cancer That Was Removed By Surgery  
Institutional Principal Investigator: Patrick Ross, MD  
Co-Investigator: Bo H Chao, MD

2012–2013    CALGB 30801  
Title: Gemcitabine Hydrochloride or Pemetrexed Disodium and Carboplatin With or Without Celecoxib in Treating Patients With Advanced Non-Small Cell Lung Cancer  
Institutional Principal Investigator: Gregory A Otterson, MD  
Co-Investigator: Bo H Chao, MD

2012–2013    RTOG 1016  
Title: Radiation Therapy With Cisplatin or Cetuximab in Treating Patients With Oropharyngeal Cancer  
Institutional Principal Investigator: Maura L Gillison, MD  
Co-Investigator: Bo H Chao, MD

2012–2015    E 5508  
Title: Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC  
Institutional Principal Investigator: Gregory A Otterson, MD  
Co-Investigator: Bo H Chao, MD

2018–2023    Lung-MAP S1800A  
Title: Phase II Randomized Study of Ramucirumab and Pembrolizumab Versus Standard of Care in Advanced Non-Small-Cell Lung Cancer Previously Treated With Immunotherapy  
Principal Investigator: Karen L Reckamp, MD  
Industry Sponsor (Lilly) Medical Lead: Bo H Chao, MD

2022–2023    SWOG S2302

Title: Pragmatica-Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer  
Principal Investigator: Karen L Reckamp, MD  
Industry Sponsor (Lilly) Medical Lead: Bo H Chao, MD

## **SELECTED PRESENTATIONS AND INVITED LECTURES**

### **Departmental:**

2011 UWCCC Grand Rounds. “The Role of Tumor Microenvironment in Oncolytic Virotherapy in Lung Cancer.” August.

UWCCC Grand Rounds. “2011 ASCO Annual Meeting Updates: Lung Cancer.” September.

2015 Lilly Oncology Lecture Series. “Lung Cancer Therapy.” April.

2024 Puma Oncology Lecture Series. “Extensive Stage Small Cell Lung Cancer and Hormone Receptor-Positive HER-2-Negative Metastatic Breast Cancer Landscape Relevant to Alisertib Development.” February.

### **Institutional:**

2023 Lilly Breakthrough Medicines Forum. “Pragmatica-Lung (S2302): A registrational and simplified pragmatic trial for ramucirumab + pembrolizumab. How to develop treatment for FDA registration in a cost-efficient way?” February.

### **National/International:**

2000 ASME International Mechanical Engineering Congress and Exposition, Orlando, FL. “Cryo, hyper, or both? Investigating combination cryo/hyperthermia in the dorsal skin flap chamber.” November. With Hoffmann NE, Bischof JC.

2003 Bioengineering Conference, Key Biscayne, FL. “Cryosurgery of normal and LNCaP Pro 5 human prostate tumor tissue in the dorsal skin flap chamber.” June. With Bischof JC.

40<sup>th</sup> Annual Meeting of the Society for Cryobiology, Coimbra, Portugal. “Pre-existing inflammation augments cryo-injury in vivo.” September. With Bischof JC.

ASME International Mechanical Engineering Congress and Exposition, Washington, D.C. “Pre-existing inflammation induced by TNF-alpha augments cryosurgery on human prostate cancer.” November. With Bischof JC.

2007 Internal Medicine 2007, American College of Physicians Annual Scientific Meeting, San Diego, CA. “Fatal Loeffler’s endocarditis due to hypereosinophilic syndrome.” April.

Internal Medicine 2007, American College of Physicians Annual Scientific Meeting, San Diego, CA. “Granulocytic sarcoma of the larynx causing dysphagia.”

April.

Internal Medicine 2007, American College of Physicians Annual Scientific Meeting, San Diego, CA. "Bcl-2 family proteins may work downstream of Akt pathway in inhibiting the apoptosis of small cell lung cancer cells." April. With Litz J, Krystal GW.

2008 Society of General Internal Medicine 31<sup>st</sup> Annual Meeting, Pittsburgh, PA. "Methicillin-resistant Staphylococcus aureus bacteremia due to prostatic abscess." April. With Kidd JM, Dow AW.

Internal Medicine 2008, American College of Physicians Annual Scientific Meeting, Washington, DC. "The Bcl-2 family proteins inhibitor ABT-737 and the selective tyrosine kinase inhibitor imatinib inhibit small cell lung cancer growth synergistically." May. With Litz J, Krystal GW.

2011 AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics, San Francisco, CA. "The inhibitory effect of tumor microenvironment on oncolytic virotherapy in lung cancer." November. With Sung KE, Yin J, Beebe DJ.

2012 University of Maryland Greenebaum Cancer Center Grand Rounds, Baltimore, MD. "The inhibitory effect of tumor microenvironment on oncolytic virotherapy in lung cancer." January.

## **TEACHING**

2012 Master of Physician Assistant Studies Program, "Lung Cancer." University of Wisconsin. February.

2012 Head and Neck Cancer Case Review. The Ohio State University. September.

2013 Hematology and Oncology Fellowship Program, "Preoperative Chemotherapy for Lung Cancer." The Ohio State University. April.

2013 Hematology and Oncology Fellowship Program, "Non-Small Cell Lung Cancer – Advanced." The Ohio State University. November.

2013 Oncology Interest Group, "Medical Student Lung Cancer Panel." The Ohio State University. December.

## **GRANTS AND MONETARY AWARDS**

### **Completed Research Support:**

T32 CA009614-21	McNeel (PI)	07/01/2010 – 06/30/2012
Physician Scientist Training in Cancer Medicine		
The purpose of this program is to enhance research training opportunities at the University of Wisconsin for physician-scientists in the field of cancer medicine.		
Role: Trainee		

## **HONORS AND AWARDS**

### **Undergraduate:**

1995 – 1999	Dean's List (10 quarters)
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1999                    *Magna Cum Laude* graduate, University of Minnesota, Twin Cities,  
MN

**Post Graduate:**

2002    BME Department Head Award, BMEI Graduate Student Poster  
Session, Brooklyn Center, MN

2003    First Place, MS Student Paper Competition, Bioengineering  
Conference,  
Key Biscayne, FL

2004                    Finalist, Distinguished Master's Thesis Award,  
Midwestern Association of Graduate Schools

2006                    Housestaff Diagnostician Award,  
Medical College of Virginia, Virginia Commonwealth University

2007    Finalist, Clinical Vignette Poster 1, American College of Physicians  
(ACP) National Associates Competition, San Diego, CA

Finalist, Clinical Vignette Poster 2, ACP National Associates Competition,  
San Diego, CA

Finalist, Research Poster, ACP National Associates Competition,  
San Diego, CA

2008    Finalist, Research Poster, ACP National Associates Competition,  
Washington, DC

Housestaff Diagnostician Award,  
Medical College of Virginia, Virginia Commonwealth University

Scholar's Prize for Excellence in Scholarship during Residency  
Medical College of Virginia, Virginia Commonwealth University

2010    NIH T32 CA009614-21 "Physician Scientist Training in Cancer  
Medicine" training grant

AACR/ASCO Methods in Clinical Cancer Research Workshop Participant

**Professional:**

2020    Q4 2020 Lilly Innovator Award "for proposing a study design and  
patient population that would potentially change the paradigm for targeted  
agents in adjuvant non-small cell lung cancer"