



SUMMIT BIOLABS DEVELOPS TEST FOR HEAD AND NECK CANCERS

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Head and neck cancer is the common term that encompasses a complex spectrum of diseases. The heading includes cancers that start in the nasal cavity, sinuses, lips, mouth, thyroid glands, salivary glands, pharynx, or larynx, yet methods for early detection of any have remained elusive. Fulfilling this need for improved diagnostic tools has become the mission of Summit Biolabs, a University of Colorado Anschutz Medical Campus startup, and its molecular oncologist founder, Shi-Long Lu, MD, PhD.

Summit Biolabs's first product in development is called HNKlear, which tests for head and neck cancer recurrence following front-line treatment by detecting certain modifications to tumor DNA. What sets it apart is that HNKlear is a liquid biopsy test using samples

at CU Anschutz. Dr. Song recognized the clinical need for monitoring cancer recurrence to choose the best therapies for the patient, and Dr. Lu recognized the potential for using microRNAs as a genetic biomarker and saliva as the sample. Together with their research team, they have devised a gamut of clinical utilities for HNKlear, ranging from use as a diagnostic tool to the ability to monitor progression and recurrence in patients.

More than just research and development has been occupying Dr. Lu's time. Summit Biolabs is the brainchild of over a year of after-work and behind-the-scenes planning and organization. Despite all of his scientific expertise, Dr. Lu found himself in a strange, new world, that of patents and business startups, in working to bring Summit Biolabs to fruition and HNKlear to market. To

and now advisor to Summit Biolabs; Bob Blomquist, healthcare industry executive and now CEO of Summit Biolabs; Brian Harry, MD, PhD, clinical pathologist at CU Anschutz and now Chief Laboratory Officer; and Abby Wright, senior executive in reimbursement, and now advisor to Summit Biolabs.

While they have received the first notice of allowance of HNKlear's patent, filed with the assistance of Summit Biolabs's attorney and Heather Callahan, Portfolio Manager at CU Innovations, Dr. Lu is not resting on his laurels. The list of immediate objectives for HNKlear includes filing for international patent protection, validating clinical utilities beyond monitoring, developing its use as guidance for personalizing patient therapies, and collaborating with pharmaceutical companies on development and distribution.

About Shi-Long Lu, MD, PhD:

Dr. Lu received his M.D. degree from China Medical University, and his Ph.D. Degree on Molecular Oncology from Tokyo Medical and Dental University. He completed his post-doctoral training in the Howard Hughes Medical Institute Lab at the Case Western Reserve University. He was an Assistant Professor of Otolaryngology, and Dermatology at the Oregon Health & Science University. He is currently an Assistant Professor of Otolaryngology, Dermatology, and Pathology at the University of Colorado Denver School of Medicine.

from an obvious and abundant source: saliva. As Dr. Lu noted, saliva is a natural resource given its ready availability and the anatomic location of most head and neck cancers. The development of HNKlear drew on a number of Dr. Lu's experiences, marrying his postdoc work on a noninvasive test for colorectal cancer, which evolved over time into the Cologuard® test from Exact Sciences, with his chosen specialization in head and neck squamous cell carcinoma. His familiarity with both laboratory and clinical research has pushed Summit Biolabs to thoroughly explore the potential of HNKlear.

To bring the clinic and the laboratory together, Dr. Lu collaborated with Dr. John Song, a surgical oncologist and Director of Head and Neck Surgery

help him make the leap to scientist entrepreneur, Dr. Lu has relied on both his network and the services offered by CU Innovations.

Early funding for HNKlear came from the SPARK program, and since their introduction, Dr. Lu has looked to SPARK and CU Innovations for "help, training, and advocating for scientists and clinicians to become scientist entrepreneurs and know what the business world looks like." Specifically, he participated in the SPARK program for step-by-step trainings in intellectual property rights, market research, business team formations, and investments. What Dr. Lu has found most beneficial of all has been the industry and business connections, in particular: Stan Lapidus, founder of Exact Sciences, serial entrepreneur,

Their most ambitious target is to make HNKlear available as an early screening test in medical, and even dental, offices. Dr. Lu once thought the widespread accessibility of a test like HNKlear for early cancer screening would be a tremendous hurdle. These days, he's heartened to see it becoming closer to reality as dental offices shift towards providing more general practitioner services.

Looking even further ahead, Dr. Lu has clear ambitions for Summit Biolabs. Expansion plans include the development of tests based not just on saliva but also on other bodily fluids, such as sputum and cervical discharge, and the detection of not just head and neck squamous cell carcinoma but all types of squamous cell carcinomas, such as those in lung, esophagus, or cervical areas.