



October 4, 2022

Press release

A Transformational Year:

ImaginAb expands Pipeline to include Radiopharmaceutical Therapies, enters Multiple Partnerships, and Drives Forward Development of Investigational CD8 ImmunoPET Agent

Los Angeles, California, USA, October 4th, 2022 – ImaginAb Inc., a global biotechnology company developing 89Zr crefmirlimab berdoxam (CD8 ImmunoPET) imaging agent and next generation therapeutic radiopharmaceuticals (RPT), is pleased to provide the following business update.

Summary:

ImaginAb has made significant progress this year in its clinical development plans as it pursues the goal to achieve regulatory approval of CD8 ImmunoPET imaging agent across multiple geographies and increases the number of partnerships using this technology.

In January 2022, ImaginAb announced a major expansion of its pipeline with **four active programs** focused on the development of **Radiopharmaceutical Therapies (RPT)**.

CD8 ImmunoPET Progress:

ImaginAb continues the clinical development of CD8 ImmunoPET with a target to file a Biologics Licence Application (BLA) submission in the next two years. The clinical development program consists of company and investigator-sponsored studies.

Phase I IBM study:

In August 2021, ImaginAb completed its Phase I IBM study showing utility of CD8 ImmunoPET to detect disease pathology in Inclusion Body Myositis (IBM) patients.

Phase IIa “BOT” study:

In December 2021, ImaginAb completed recruitment of its Phase IIa “baseline-on treatment” (BOT) study and in July 2022 it concluded the 12-month follow-up process of subjects and has now entered the data analysis stage. Preliminary analyses are encouraging, and initial findings will be shared at the Society of Immunotherapy of Cancer (SITC) conference being held in Boston, in November 2022.

Phase IIb 'iPREDICT' study:

ImaginAb formally launched its **Phase IIb 'iPREDICT' study** to measure CD8 ImmunoPET imaging predictivity and prognosis, building on the data from its promising Phase IIa 'BOT' study. The study aims to enrol **80 patients over 22 sites** across US, Australia, and Europe, focusing on many cancer types including Melanoma, Merkel Cell, Renal Cell, Non-Small Cell Lung Cancer and selected solid tumors. Data is anticipated in 2024. In this study, Roche is providing access to **atezolizumab (Tecentriq®) to Non-Small Cell Lung Cancer Patients**.

Phase IIb iCiT study:

ImaginAb started recruitment in June 2022, which is being performed in conjunction with Memorial Sloan Kettering Cancer Center (MSKCC) and funded by the Melanoma Research Alliance and ImaginAb with the goal to collect whole tumor samples to provide additional supportive evidence for diagnostic performance and explore utility of CD8 ImmunoPET in the neoadjuvant setting.

ImaginAb supports the exploration and expanded use of CD8 ImmunoPET by exploring alternative indications and provision of funding to investigator-initiated studies.

COVID-19:

In June 2022, University of California Davis presented preliminary data regarding the utility of CD8 ImmunoPET in imaging COVID-19 patients.

CD8 ImmunoPET Partnership Agreements:

Over the last year, ImaginAb has signed multiple partnership agreements with several biotech and pharma companies to license its technology, demonstrating third party endorsement and establishing ImaginAb's pioneering CD8 ImmunoPET technology as integral to immuno oncology clinical trials in countries all over the world. ImaginAb has publicly disclosed and announced the following partnerships:

- Multi-year license agreement with **Bayer** to use CD8 ImmunoPET imaging agent in its oncology trials at clinical sites across multiple countries
- License agreement with international biotechnology company, **Genmab A/S**, to utilize CD8 ImmunoPET in its clinical trials, accessing ImaginAb's global supply chain
- Signed agreements with two leading iCRO's allowing them to provide ImaginAb technology more widely to pharma and biotech customers.
 - Agreement to supply global, industry-leading imaging CRO company, **Invicro LLC**, with CD8 ImmunoPET for use in pharma and biotech clinical and preclinical studies
- Partnership expansion enabling the world's largest oncology-focused imaging CRO, **Imaging Endpoints**, to supply CD8 ImmunoPET direct to biopharma for use in clinical trials in oncology, IBM, and COVID-19.

Exclusive Territorial Licensing Agreement:

In May 2022, ImaginAb signed an exclusive license agreement with **DongCheng Pharmaceutical Group**, the second largest radiopharmaceutical company in China, to utilize and commercialise CD8 ImmunoPET in pharma and biotech clinical trials in China. ImaginAb has agreed to receive substantial milestone and royalty payments.

CD8 ImmunoPET Global Manufacturing Agreements:

Having entered into multiple productive clinical supply and global manufacturing agreements (GMA) this year, ImaginAb has established a leading global network for manufacturing and distributing its CD8 ImmunoPET imaging agent. These GMA agreements include:

- Turkey-based radiopharmaceuticals company, **Monrol**, to supply, manufacture and distribute CD8 and radiopharmaceutical isotopes for ImaginAb's iPREDICT study and other partner pharma studies
- **PharmaLogic**, the fastest growing radiopharmaceutical manufacturer in North America, to manufacture and distribute CD8 ImmunoPET for ImaginAb. On September 12th, 2022, the GMP contract manufacturing organization (CMO) successfully delivered the first tracer dose to a US clinical site. The production launch increased ImaginAb's manufacturing and distribution capacity in North America, providing additional flexibility in clinic scheduling for injection and scan for immunoncology clinical trials.
- **DuChemBio**, South Korea's leading radiopharmaceutical company, agreed to supply, manufacture, and distribute CD8 ImmunoPET to pharma sponsored trials in South Korea and other Asian countries which are new to ImaginAb.

RadioPharmaceutical Therapy (RPT) Progress:

ImaginAb announced in summer 2021 that it had active programs developing RPT agents based on its proprietary minibody and cys-dibody platforms. In less than one year, the team have identified potential clinical candidates for two cancer targets and is currently initiating IND enabling studies. To support this work and to secure isotope supply for clinical studies and commercialization, ImaginAb announces the following supply agreement:

- Next-generation nuclear technology company, **SHINE Technologies**, agree to supply (n.c.a.) lutetium-177 for the clinical development of ImaginAb's investigational radiopharmaceuticals

Commenting on ImaginAb's progress this year, Ian Wilson, Chief Executive Officer of ImaginAb, said:

"The leadership team at ImaginAb is excited to be making progress with our own clinical studies as we pursue our goal to file BLA submissions for 89Zr crefmirlimab berdoxam across multiple geographies, in addition we have expanded our pipeline further into the radiopharmaceutical therapy field.

We have had a transformational year which has seen ImaginAb complete many key development milestones. We currently have licensing agreements with more than fourteen different customers and repeat business from existing customers including Astra Zeneca, Pfizer and Boehringer Ingelheim, enable use of our product in their clinical trials. We look forward to continuing our progress into 2023.”

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About ImaginAb

ImaginAb is a clinical stage, revenue-generating biotech company, with offices in the United States and the United Kingdom. ImaginAb is focused on developing next generation imaging and therapeutic radiopharmaceuticals (RPT) based on their proprietary Minibody and Cys-diabody platform. 89Zr crefmirlimab berdoxam (CD8 ImmunoPET agent) is currently in Phase II clinical trials and is used by numerous Pharmaceutical and Biotech companies in their immuno-oncology clinical trials.

The company has a clearly defined purpose and growth strategy, enabling them to work closely with research and commercial partners to transform patient care, and help people live better and healthier lives. For more information visit www.imaginab.com

About CD8 ImmunoPET

The 89Zr crefmirlimab berdoxam (CD8 ImmunoPET) imaging agent is an 89Zr-labelled minibody that has been designed to bind to the CD8 receptor on human T cells and is used for quantitative, non-invasive PET imaging of CD8 T cells in patients. CD8 T cells are the main effector cells involved in the immune response against tumor cells induced by immunotherapies and they also play a key role in multiple autoimmune diseases. As such, quantitative imaging of CD8 T cells may be used to diagnose the immune status of a patient, to measure the efficacy of immunotherapies and has potential to predict patient outcomes.

