Q&A
CUSTOMER SPOTLIGHT


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IN THIS CUSTOMER SPOTLIGHT, *Jessika Wynendaele*, Business Development Director at ProBio, sat down with *Marika Nestor* and *Fredrik Frejd* of Akiram Therapeutics to discuss target selection, clinical translation, and the lessons learned while advancing 177Lu-AKIR001, a next-generation radiopharmaceutical therapy, into the clinic.

Could you briefly introduce Akiram Therapeutics and the program you are developing?

"Akiram Therapeutics is a Swedish clinical-stage biotech focused on targeted radiopharmaceutical therapies for cancer. Our lead candidate, 177Lu-AKIR001, combines a proprietary CD44v6-targeting antibody with lutetium-177 and is currently being evaluated in a first-in-human Phase I study at Karolinska University Hospital. It's been exciting to see the program progress from discovery into the clinic, where we're now generating our first human data."

Why did you develop AKIR001?

"We wanted to address a significant unmet need for patients with advanced CD44v6-positive solid tumors, where treatment options are often limited. Because CD44v6 is expressed across several aggressive cancer types, the platform also has potential beyond a single indication. Our goal is to deliver radiation directly to tumor tissue while minimizing exposure to healthy organs."

Why was a radiolabeled antibody the right approach?

"From the outset, we felt CD44v6 was particularly well suited to antibody-based radiopharmaceutical therapy. Combining a highly specific antibody with an optimized conjugation strategy gave us confidence that the target was a strong fit for targeted radionuclide therapy."

What were some of the biggest challenges during development?

"Moving from a promising research program to a clinical product was definitely one of the biggest challenges. Manufacturing, radiolabeling, quality control, and clinical logistics all need to work together seamlessly. It also takes strong collaboration across industry, academia, and healthcare."

What key lessons have you learned along the way?

"One of the biggest lessons is that the antibody, conjugation strategy, radionuclide, and radiolabeling process can't be developed separately. They need to be treated as one integrated product. We've also seen how valuable quantitative imaging can be. Using lutetium-177 allows us to combine therapy and imaging, giving us an early understanding of biodistribution and absorbed dose in patients."

When selecting development and manufacturing partners, what mattered most?

"Quality systems, regulatory expertise, and manufacturing capabilities were all essential. Beyond that, we really valued responsiveness, flexibility, and clear communication. Development programs evolve quickly, so you need partners who can adapt alongside you."

What were the key success factors in advancing the program into Phase I?

"It came down to combining strong science with the right expertise. We benefited from deep knowledge across CMC, radiochemistry, dosimetry, nuclear medicine, and oncology, all supported by a clear translational strategy."

How did you know the program was ready for first-in-human studies?

"We saw a very consistent story emerge from the preclinical data. AKIR001 demonstrated strong tumor specificity, encouraging antitumor activity, and favorable biodistribution. Together, those findings gave us the confidence to move into clinical evaluation."

What have been the key milestones in the program's journey so far?

"Starting manufacturing was a major step, and launching the Phase I study was another. But seeing the first patient images was probably the highlight. Watching AKIR001 accumulate in tumor tissue while clearing from the rest of the body provided encouraging early proof of concept for the targeting strategy."

Finally, what has been most important to the success of AKIR001 so far?

"Collaboration has been key. Developing AKIR001 as an integrated product required not only the right expertise, but also people who were genuinely committed to moving the program forward. We've been fortunate to work with dedicated collaborators throughout the journey. Another exciting aspect of radiopharmaceutical development is how much you can learn early. Even at this stage, we can already see where the drug goes, how effectively it targets tumors, and how much radiation is delivered. That provides valuable proof-of-concept data long before therapeutic efficacy can be fully evaluated."

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