

Medical Milestones

Tiny Biotechs Get Giant Results In Leukemia Treatment

(NAPSA)—A revolutionary new treatment for relapsed chronic lymphocytic leukemia (CLL) may soon be available. For decades, the only treatment for CLL was toxic chemotherapy that provided limited benefit. However, over the last 20 years, major strides have been made in the quest to develop a new treatment that is both safe and effective, and each new development can be attributed to efforts made by a tiny biotech company.

In fact, very recently, a tiny biotech called TG Therapeutics released exciting data concerning an innovative new treatment, TG-1101 (ublituximab), for CLL patients that builds on those past successes.

So, in essence then, TG's success really begins decades ago. It was back in 1996 when researchers at a tiny company called Idec Pharmaceuticals discovered Rituxan. Rituxan was the first drug to harness the immune system to treat leukemias and lymphomas, and all these years later it is still hailed as one of the greatest breakthroughs in the treatment of cancer.

The next breakthrough occurred in 2010, when another small biotech company, Pharmacyclics, developed ibrutinib. It was referred to as the magic pill for CLL. About half the patients who relapsed after chemotherapy and Rituxan responded to ibrutinib. Unfortunately, ibrutinib alone was not the answer for all patients.

"Ibrutinib has been a great addition to our CLL armamentarium. However, we have long believed that ibrutinib alone may not be enough, particularly for patients with high-risk disease," said Dr. Kathryn Kolibaba, who is the Associate Chair of the Hematology Research Committee for US Oncology and practices at Compass Oncology in Vancouver, Washington.

That is why, in 2013, Dr. Kolibaba and her colleagues at US Oncology partnered with TG Therapeutics to research the potential of TG-1101 as a treatment option for CLL. What intrigued them about TG's compound was that it was similar to Rituxan yet it was designed to



Researchers have discovered a way to encourage the body's own immune system to fight off cancer.

be much more effective due to a technique that enabled TG-1101 to better engage the immune system to more effectively kill the cancer cells.

Alone, TG-1101 is an exciting advance, but the major breakthrough came about when TG-1101 was combined with ibrutinib. "We were excited to see if we could create a really potent combination that was safe for our patients," stated Dr. Kolibaba. In TG's first Phase 2 clinical trial evaluating the chemotherapy-free combination, published in the prestigious *British Journal of Haematology*, nearly all patients treated achieved great benefit and experienced a major reduction in their disease.

A Phase 3 clinical trial for the same combination followed, and confirmed the impressive Phase 2 findings. Investigators again found that the addition of TG-1101 to ibrutinib improved the response rate by more than 70 percent as compared to ibrutinib alone.

"These are the first Phase 3 results showing that we can dramatically increase the remission rate for CLL patients taking ibrutinib without the addition of toxic chemotherapy and is truly a great advance for patients," stated Dr. Kolibaba.

More information about TG Therapeutics and TG-1101 (ublituximab) can be found at www.tgtherapeutics.com and www.BCellClinicalTrials.com.