

Inotuzumab ozogamicin is an investigational agent for adults with relapsed/refractory acute lymphoblastic leukemia (ALL) and has not been approved by regulatory agencies.

## ABOUT INOTUZUMAB OZOGAMICIN

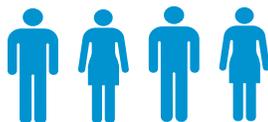
Inotuzumab ozogamicin is an investigational antibody-drug conjugate (ADC) comprised of a monoclonal antibody (mAb) targeting CD22, a cell surface antigen found on cancer cells in almost all B-ALL patients, linked to a cytotoxic agent.<sup>1,2</sup> When inotuzumab ozogamicin binds to the CD22 antigen on malignant B-cells, it is thought to be internalized into the cell, where the cytotoxic agent calicheamicin is released to destroy the cell.<sup>3</sup>

## ABOUT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

Acute lymphoblastic leukemia (ALL) is an aggressive cancer of the bone marrow and blood that can be fatal within a matter of months if left untreated.<sup>4</sup>

While many potential treatments have been studied, only a limited number of medicines for relapsed or refractory adults with ALL have been approved by the FDA and other regulatory authorities in the past decade.

The current standard treatment is intensive, lengthy chemotherapy with the goal of halting the signs and symptoms of ALL (called hematologic remission) and becoming eligible for a stem cell transplant.<sup>4</sup>



## UNMET NEEDS IN ADULT ALL

### Statistics & Patient Characteristics

- In 2016, it is estimated that 6,590 cases of ALL will be diagnosed in the United States, with about 4 in 10 cases occurring in adults.<sup>5</sup>
- Older patients with ALL may have other medical problems (known as comorbidities), including heart, lung or kidney disease or diabetes mellitus. If these are present, the doctor may select less toxic drugs or decrease the dosage and frequency of treatment.<sup>6</sup>
- While significant strides have been made in treating children with ALL, the opposite is true for adults with the disease. Only 20 to 40 percent of adults with ALL are cured with current treatment regimens,<sup>7</sup> and approximately 1,430 deaths will occur in 2016.<sup>5</sup>

### About Relapsed/Refractory Adult ALL

- Approximately half of the 2,000 U.S. adults who learn they have ALL this year will not respond to commonly used chemotherapy agents (e.g., be refractory) or will eventually see their disease return (e.g., relapse).<sup>5</sup>
- The outlook for adults with relapsed or refractory ALL is poor. These patients have already tried and failed commonly used treatments, leaving very few treatment options available to them. Nine out of ten of these patients will not survive more than five years.<sup>8</sup>



## INOTUZUMAB OZOGAMICIN CLINICAL STUDIES IN RELAPSED/REFRACTORY ALL

Results of INO-VATE ALL trial were published in the *New England Journal of Medicine*.

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### Phase 3

- The INO-VATE ALL study, also known as Study 1022, is an open-label, randomized, Phase 3 Study evaluating the safety and efficacy of inotuzumab ozogamicin as compared with investigator-choice chemotherapy in 326 adult patients with relapsed or refractory CD22-positive ALL. This study had two primary endpoints, complete response with or without hematologic remission (CR/CRi) and OS.
- In June 2016, the full results of INO-VATE ALL were published in the *New England Journal of Medicine*. Updated results and newly available OS data were also presented at the 21st Congress of the European Hematology Association (EHA) 2016 Annual Meeting.

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### Phase 1/2

- Study 1010 (B1931010) – An open-label, Phase 1/2 study of inotuzumab ozogamicin in subjects with relapsed or refractory CD22-positive ALL.<sup>9</sup> This study is complete and is no longer enrolling patients.

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## REGULATORY MILESTONES

- Inotuzumab ozogamicin received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for ALL in October 2015.
- Pfizer is working closely with the FDA and other regulatory authorities with the aim of making inotuzumab ozogamicin available for adult patients with relapsed or refractory CD22-positive ALL.

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