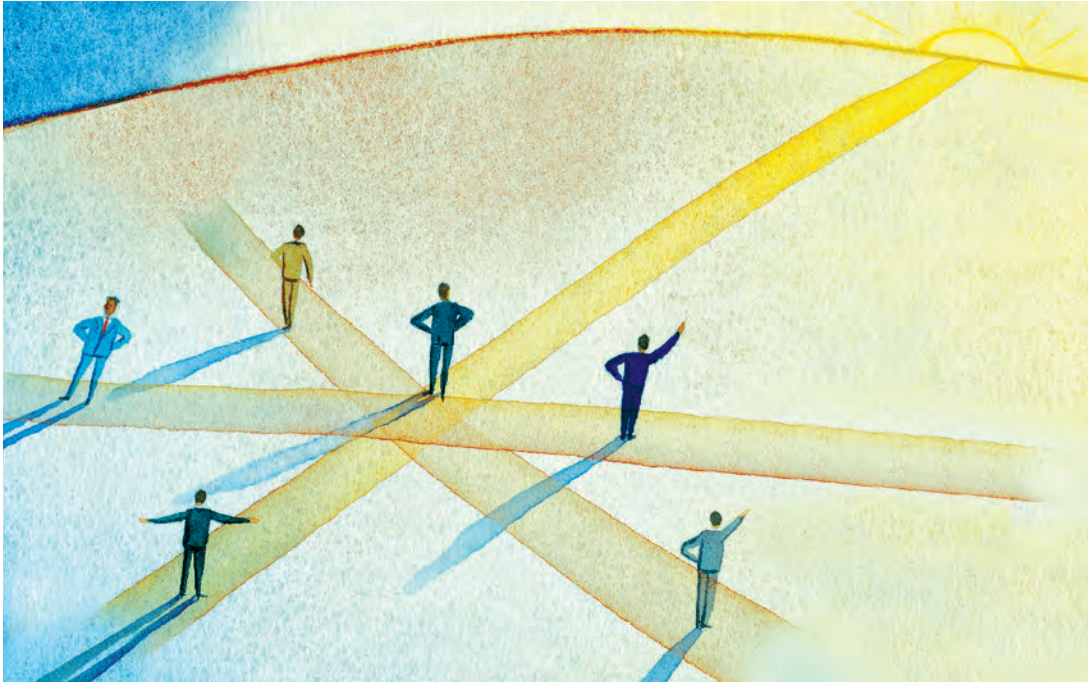


# COLORADO'S CLINICAL TRIAL LANDSCAPE

BY ADAM RUBENSTEIN



Colorado is home to a host of companies whose products are undergoing clinical trials, demonstrating a maturing bioscience community that maintains industry strengths beyond simply the discovery, research and development stages. The state claims a talented and dedicated work force of regulatory, quality and commercially-focused professionals who are successfully shepherding quality-of-life improving and lifesaving technologies through human trials and placing FDA-approved products in the treatment quiver of clinicians in the U.S. and around the world.

It is not simply the resident bioscience companies that are conducting clinical trials at a mile above sea level: There are more than 1,000 clinical trials recruiting, enrolling and treating patients throughout Colorado hospitals, universities, doctors' offices and community clinics. Many of these trials are sponsored by federal agencies such as the National Institutes of Health, the Department of Defense, and the Department of Veterans Affairs. Additionally, more than 100 public and private pharma, biopharma and device companies

are leveraging the facilities, professionals and citizens of Colorado to spearhead the world's most innovative health-care products.

Following is a snap-shot of some Colorado-based companies who are working to advance the practice of modern medicine through their pursuits of human clinical trials:

Westminster, CO-based **Allos Therapeutics** (NASDAQ: ALTH) has established itself as a commercial organization in the oncology space as it drives sales of pralatrexate in the U.S. and retains the drug's exclusive worldwide commercial rights for all indications. Based on the results of its PROPEL clinical trial, the Company intends to seek regulatory approval to market pralatrexate in Europe for the treatment of relapsed or refractory peripheral T-cell lymphoma. Allos is committed to evaluating pralatrexate both as a single agent and in combination with other therapies via ongoing clinical trials. Additional trials are planned to evaluate pralatrexate's potential clinical utility in other hematologic malignancies and solid tumor indications.

## Companies conducting Colorado-based clinical trials include:

Abbott  
 Abraxis BioScience  
 Allergan  
 Amlyn Pharma  
 Astellas Pharma  
 AstraZeneca  
 Biogen Idec  
 BiPar Sciences  
 Boehringer Ingelheim  
 Bristol-Myers Squibb  
 Celgene  
 Clavis Pharma  
 Cubist Pharma  
 Eli Lilly  
 Forest Laboratories  
 Genentech  
 GlaxoSmithKline  
 Johnson & Johnson  
 MedImmune  
 Medtronic  
 Merck  
 Novartis  
 Novo Nordisk  
 Ortho-McNeil  
 Otsuka  
 Pfizer  
 Sanofi-Aventis  
 Schering-Plough  
 St. Jude Medical  
 Takeda  
 Wyeth  
 Zimmer

**Clinical Pipeline:** Pralatrexate pipeline is currently being examined in hematological malignancies in peripheral T-cell lymphoma (Phase III), in cutaneous T-cell lymphoma (Phase I), lymphoma (Phase II) and B-cell non-Hodgkin's lymphoma (Phase II). The compound is also being examined in solid tumors in non-small cell lung cancer (Phase III), bladder cancer (Phase II) and breast cancer (Phase II).

Boulder, CO-based **Array Biopharma** (NASDAQ: ARRY) is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat cancer and inflammatory diseases. The Company's drug development pipeline includes candidates designed to regulate therapeutically important target proteins and those aimed at significant unmet medical needs. In addition, a number of leading pharmaceutical and biotechnology companies are collaborating with Array to discover and develop drug candidates across a broad range of therapeutic areas.

**Clinical Pipeline:** Phase I trials in both HER2-positive metastatic breast cancer and

HER-family cancer patients showed that ARRY-543 was generally well tolerated and demonstrated evidence of tumor regression and prolonged stable disease in EGFR- and HER2-expressing cancers. A Phase Ib study of ARRY-543, in combination with Xeloda, Taxotere and Gemzar, is currently enrolling patients with solid tumors. Array continues a dose escalation in a Phase I trial with ARRY-380 to evaluate a maximum, safely tolerated dose and pharmacokinetics in patients with advanced cancer. Clinical development activities for ARRY-520 consist of a Phase I trial of ARRY-520 in patients with solid tumors, a Phase I trial in patients with AML, and a Phase I/II trial in patients with multiple myeloma. ARRY-614 has completed a single- and multiple-dose escalation study in healthy volunteers and initiated a Phase Ib/II trial in myelodysplastic syndrome. ARRY-797 has completed two Phase II trials in acute inflammatory pain using a dental pain model.

Westminster, CO-based **Cerapedics** is a medical device company enhancing the science of bone repair by developing and commercializing osteobiologic products based on

P-15™, a proprietary small peptide anorganic bone mineral.

**Clinical Pipeline:** Cerapedics is currently enrolling patients in a Phase III clinical trial of P-15 Bone Putty for single level anterior cervical discectomy and fusion procedures. The trial will assess the safety and effectiveness of P-15 Bone Putty as a substitute for local autologous bone when applied in instrumented anterior cervical discectomy and fusion with use of a structural allograft ring in patients with degenerative cervical disc disease.

Louisville, CO-based **GlobeImmune** is a biopharmaceutical company focused on the development of therapeutic vaccines called Tarmogens® for the treatment of cancer and infectious diseases. Tarmogens generate activated killer T-cells designed to locate and eliminate cancer cells and/or virally infected cells. In May 2009, the company announced a global partnership with Celgene focused on the discovery, development and commercialization of multiple product candidates for the treatment of cancer.



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**Clinical Pipeline:** GI-5005, in a Phase IIb trial for chronic hepatitis C, expresses a fusion protein encompassing sequences from both HCV NS3 and Core proteins. NS3 and Core, abundantly expressed in infected cells, are required for viral replication and contain targets that are recognized by both CD4+ helper and CD8+ killer T-cells. Both the Core and NS3 proteins are highly conserved among HCV genotypes 1a and 1b, the HCV strains most prevalent in the U.S. GI-5005 is designed to complement both the current standard of care and emerging novel therapies for HCV. GI-4000, for mutated-Ras mediated cancers, causes the targeted elimination of any cell containing mutations in the ras oncogene, and is being investigated in Phase II clinical trials for the treatment of pancreas, non-small cell lung and colorectal cancers.


Greenwood Village, CO-based **Omni Bio Pharmaceutical's** (OTCBB: OMBP) strategy is to advance existing and novel therapies it believes have the potential to quickly move through clinical trials and advance to commercialization. This strategy is based on licensing issued patents and pending patent applications

that cover new uses for an existing FDA-approved drug, Alpha-1 antitrypsin (AAT), which is currently used in the treatment of emphysema in AAT-deficient patients.

**Clinical Pipeline:** Initial patients have been infused in the company's FDA-cleared Phase I/II human clinical trial of AAT in recently diagnosed Type 1 diabetics at the Barbara Davis Center for Childhood Diabetes at the University of Colorado, Denver Anschutz Medical Campus. The Phase I/II clinical trial is evaluating the potential of AAT to halt or reduce the deterioration of islet beta cells that causes Type 1 diabetes. While Type 1 diabetics will experience islet beta cell destruction, the trial evaluates whether AAT treatment may help stop the course of the disease in newly diagnosed diabetics who may have remaining islet beta cells.

Boulder, CO-based **N30 Pharmaceuticals** is focused on restoring nitric oxide (NO) balance by decreasing disease-associated accelerated breakdown of NO's primary depot, S-nitrosoglutathione (GSNO). To date, pharmacologic inhibition in mice of S-nitrosoglutathione reductase (GSNOR) or

GSNOR knock-out have shown benefit in models of respiratory (asthma and Chronic Obstructive Pulmonary Disease COPD), cardiovascular (hypertension and endothelial dysfunction) and Inflammatory Bowel Disease (IBD). N30's drugs target nitric oxide reductase (NOR), the most important of which is GSNOR, an enzyme of central importance in human health and disease. GSNOR is a selective enzyme that breaks down GSNO, the most abundant low molecular weight source of the human body's nitric oxide and is long known to be a potent inhibitor of inflammation. GSNO also positively affects vascular and airway smooth muscle tone as well as control of breathing. Inhibition of GSNOR increases the levels of endogenous GSNO.

**Clinical Pipeline:** N30 announced in the fourth quarter of 2010 that it has dosed the first human subject with N6022, a first-in-class inhibitor of GSNOR. N6022 is the lead product in N30's portfolio of drugs designed to treat asthma, COPD and IBD. The initial Phase I testing in healthy subjects is designed to evaluate the safety, tolerability and pharmacokinetics of single, increasing intravenous dosages. 

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