



NEWSROOM

July 28,
2008—[CytoDyn
on Target With
Target for
Electronic FDA
Application](#)

July 2,
2008—[CytoDyn
Begins GMP
Manufacturing of
its
First-In-Class
AIDS Drug.](#)

June 5,
2008—[CytoDyn
to Meet With
Quest Clinical
Research to
Finalize Phase II
Strategy for
Novel AIDS
Drug.](#)

May 19,
2008—[CytoDyn
Appoints Dr.
Nader Z.
Pourhassan
Chief Operating
Officer.](#)

CytoDyn on Target With Target for Electronic FDA Application

Glorieta, NM and New York, NY— July 28, 2008 — Business Wire — CytoDyn, Inc. (Pink Sheets:CYDY) has selected [Target Health, Inc.](#) for the preparation and electronic filing of CytoDyn's upcoming FDA application using Target Health's proprietary e*CRF® system. The advantage of Target Health is based on its core expertise in regulatory affairs and clinical research, and its paperless approach to FDA filings, including submission of electronic INDs (eIND) and electronic common technical documents (eCTD). Paperless clinical research and the electronic filing of regulatory documents reflect a growing trend in the pharmaceutical industry. Dow Pharmaceutical Sciences (NYSE:DOW), King Pharmaceuticals (NYSE:KG) and Pain Therapeutics (Nasdaq:PTIE) are among the leading pharmaceutical companies that have helped pioneer this modernization of the industry.



About CytoDyn

CytoDyn, which expects its first electronic application to be submitted to the FDA in about eight weeks, is developing Cytolin®, a first-in-class drug that uses the human immune system to help control HIV infection. Because a well-functioning immune system can usually control a virus regardless of its subspecies, this could potentially provide a “salvage” therapy for those failing antiretroviral therapy. For the same reason, it might help prevent drug-resistance strains of HIV from ever emerging when used in combination with traditional antiretroviral drugs.

At the height of the AIDS epidemic, community physicians treated about 200 patients experimentally with a generic form of Cytolin® to delay the need for antiretroviral therapy, which had not yet become fully available, as previously reported by [CBS-TV News](#). This might also turn out to be a way of using a drug like Cytolin® since, despite the great strides that have been made in treating HIV/AIDS, the [U.S. Department of Health and Human Services](#) recommends delaying the use of antiretroviral drugs until the disease has progressed to the point where such drugs are indicated.

CytoDyn has not yet decided which of these potential uses for Cytolin® it will pursue as an initial indication, pending completion of its upcoming clinical trial. The upcoming trial will re-investigate dosing and is designed to be pristine in order to qualify as a proof-of-principle study. Although not the first clinical trial of Cytolin®, it will be the first clinical trial sponsored by CytoDyn, whose [CEO](#) invented this treatment. The Principal Investigator is [Dr. Jay Lalezari](#), a prominent clinical researcher in San Francisco California specializing in HIV/AIDS. Dr. Lalezari was instrumental in defining the parameters of a proof-of-principle study under the current treatment guidelines.

About Target Health

Target Health, Inc. is a New York City-based full service e*CRO with full-time staff dedicated to all aspects of Regulatory Affairs, Clinical Research, Biostatistics, Data Management, Paperless Clinical Trials (Target e*CRF®, Target Document®, Target Encoder®, Target e*CTMS™), Software Development, Strategic Planning and Drug/Device/Biologic Development. Target Health, Inc. currently represents 28 companies at the FDA and two companies at Health Canada. Target's clients include Fortune 100 companies as well as many smaller companies. A complimentary newsletter, "[On Target](#)," is available from Target Health, Inc. for those interested in contemporary drug-development issues.

"We were impressed with the broad experience, rapid response, and flexibility of Target Health, Inc., and gained a sense of security from the positive outcome of an on-site audit of that company conducted by the FDA," said Dr. Nadar Pourhassan, CytoDyn's COO.

Disclaimer

This press release contains forward-looking statements that are not historical facts. CytoDyn's management makes forward-looking statements concerning the Company's expected future operations, performance and other developments. These forward-looking statements are necessarily estimates based upon current information and projections and involve a number of risks and uncertainties, including but not limited to, the failure of preliminary results from clinical studies to reflect the results from more comprehensive studies. There can be no assurance that such risks and uncertainties, or other factors, will not affect the accuracy of such forward-looking statements. It is impossible to identify all the factors that could cause actual results to differ materially from those estimated by CytoDyn. They include, but are not limited to, government regulation, managing and maintaining growth, victimization by white-collar offenders, and the effects of adverse publicity, litigation, competition, and other factors that may be identified from time to time in the Company's announcements.