First self-administered antibody therapy for HIV in late-stage clinical trials

CytoDyn Annual Meeting of Stockholders
August 24, 2017
Forward-Looking Statements

This presentation includes forward-looking statements and forward-looking information within the meaning of United States securities laws. These statements and information represent CytoDyn’s intentions, plans, expectations and beliefs, and are subject to numerous risks, uncertainties and other factors, of which many are beyond CytoDyn’s control. These factors could cause actual results to differ materially from such forward-looking statements or information. The words “believe,” “estimate,” “expect,” “intend,” “attempt,” “anticipate,” “foresee,” “plan,” and similar expressions and variations thereof, identify certain of such forward-looking statements or forward-looking information, which speak only as of the date on which they are made.

CytoDyn disclaims any intention or obligation to publicly update or revise any forward-looking statements or forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable law. Readers are cautioned not to place undue reliance on these forward-looking statements or forward-looking information. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of and expense associated with research, development, regulatory approval, and commercialization of CytoDyn’s products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; future clinical trial data on CytoDyn’s products and product candidates will be unfavorable; funding for additional clinical trials may not be available; CytoDyn’s products may not receive marketing approval from regulators or, if approved, may fail to gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development may reduce the commercial potential of CytoDyn’s products; CytoDyn, its collaborators or others may identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, or other adverse events.

CytoDyn is also subject to additional risks and uncertainties, including risks associated with the actions of its corporate, academic, and other collaborators and government regulatory agencies; risks from market forces and trends; potential product liability; intellectual property litigation; environmental and other risks; and risks that current and pending patent protection for its products may be invalid, unenforceable, or challenged or fail to provide adequate market exclusivity. There are also substantial risks arising out of CytoDyn’s need to raise additional capital to develop its products and satisfy its financial obligations; the highly regulated nature of its business, including government cost-containment initiatives and restrictions on third-party payments for its products; the highly competitive nature of its industry; and other factors set forth in CytoDyn’s Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission.
Accomplishments over the Past Year

- Continuing enrollment on Phase 2b/3 Combination Therapy trial
- Initiated enrollment in Phase 2b/3 Monotherapy trial and is well underway
- Initiated patient treatment in Phase 2 GvHD trial
- Initiated rollover trial to accommodate patients who successfully complete Combination Therapy trial
- Continued to support patients in Phase 2b monotherapy trial
  - Now experiencing 3 years of successfully suppressed viral load and continuing
Accomplishments over the Past Year

• Further advanced preparations for manufacturing cGMP PRO 140 and engaged a new CMO

• Presented PRO 140 clinical trial results at two scientific conferences
  • CROI – February
  • ASM – June

• Initiated several animal studies to explore non-HIV indications for PRO 140

• Raised approximately $20 million of new capital
### Trial

<table>
<thead>
<tr>
<th>Study</th>
<th>Design / Findings</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD02 Pivotal Phase 2b/3 HIV Trial</td>
<td>Combination therapy in HAART failures, 1 week efficacy + 24 weeks safety and durability</td>
<td>Primary endpoint results in 2017</td>
</tr>
<tr>
<td><strong>First path to approval</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD03 Phase 2b/3 Investigative HIV Trial</td>
<td>Long-term <strong>monotherapy</strong></td>
<td>Data in 2018</td>
</tr>
<tr>
<td><strong>Large market size</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD01 Phase 2b HIV extension study</td>
<td>Long-term <strong>monotherapy</strong> extension: 9 patients with viral load suppression nearing 3 years</td>
<td>Ongoing</td>
</tr>
<tr>
<td>CD04 Phase 2 Trial in acute Graft versus Host Disease (GvHD)</td>
<td>60 patient, 100-day trial period</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>
CD02 Pivotal Phase 2b/3 Combination Trial
Treatment-Experienced HIV-infected Patients

Prior Study Shows Viral Load Reduction
First proof-of-concept for a long-acting, self-administrable HIV drug administered weekly or bi-monthly

Pivotal Phase 2b/3 Combination Trial

- PRO 140 + HAART
- Anticipated path to 1st FDA Approval of PRO 140
- Potential for FDA with Breakthrough Therapy Designation

Primary Efficacy Endpoint:
33 patients to date

Full Protocol:
11 Patients to date with undetectable viral loads
10 Patients currently in rollover
CD02 Pivotal Phase 2b/3 Combination Trial
Enrollment of Treatment-Experienced HIV-infected Patients

Enrollment Criteria:
Resistance to ONE drug from TWO different classes
+ Limited Treatment Options
Phase 2b/3 Investigate Monotherapy Trial:
• Supported by long-term viral efficacy from Phase 2b extension study
• HIV viral load managed with HAART
• Potential for enrollment completion in 2017

48 Weeks | N = 300

Primary Endpoint:
Proportion of patients who remain on PRO 140 without experiencing virologic failure

Secondary Endpoint:
Efficacy, safety and tolerability data

Safety results to support BLA submission for PRO 140 in combination with HAART

Primary Objective:
Identify PRO 140 responders and increase responder rate above 70%

<table>
<thead>
<tr>
<th>Distribution of HIV patients</th>
<th>&lt;1cp/mL</th>
<th>&lt;40cp/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>70%</td>
<td>30%</td>
</tr>
</tbody>
</table>

Patients with initial viral load breakout exhibited a decrease in viral load with PRO 140 administered more frequently

Patients on PRO 140 monotherapy for approximately 3 years did not develop anti-drug antibodies.
• 9 patients in ongoing extension study
• 8 patients nearly three years of viral load suppression with once weekly PRO 140 injection

*Patients cite lower toxicity and fewer side effect with PRO 140 versus HAART with completely suppressed viral load*
Phase 2 Trial in Graft versus Host Disease (GvHD)

GvHD Prophylaxis Trial:
Randomized, double blind, placebo controlled,
60 patients, multicenter trial

- GvHD is potentially life-threatening complication following bone marrow transplant
- Immune systems depleted during aggressive cancer therapy for leukemia patients (AML/MDS)
- GvHD as the leading causes of death in these patients
- Plan to file for Breakthrough Designation subject to results from Phase 2 study
- Supported by remarkable animal data

Primary Endpoint:
Incidence & severity of GvHD

Secondary Endpoint:
Durability & safety

100 days | N = 60
Effect of PRO 140 on xeno-GVHD in NSG mice

- **Survival %**
  - Day: 0, 20, 40, 60, 80, 100

- **Weight gm mean ± SE**
  - Day: 0, 10, 20, 30, 40, 50, 60
  - Control vs PRO 140
  - Proportion of weight: 21.0 to 24.0
  - Difference highlighted: P < .01

- **Survival %**
  - Day: 0, 20, 40, 60, 80, 100
  - Proportion of survival: 0 to 100
  - Control vs PRO 140
  - Proportion of survival: 0 to 100
  - Difference highlighted: P < .01

- **Images**:
  - A: Control
  - B: PRO 140
BONE MARROW TRANSPLANT IS A MAJOR CAUSE OF GvHD.
# PRO 140 Important Milestones 2017/2018

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Target Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Fast Track Designation</td>
<td>Granted</td>
</tr>
<tr>
<td>HIV Breakthrough Therapy Designation (application submitted)</td>
<td>2017</td>
</tr>
<tr>
<td>Pivotal Phase 2b/3 HIV Combo Trial Primary Endpoint</td>
<td>2017</td>
</tr>
<tr>
<td>Pivotal Phase 2b/3 HIV Combo BLA (Biologic License Application) Submission</td>
<td>2018</td>
</tr>
<tr>
<td>Pivotal Phase 2b/3 HIV Combo BLA (Biologic License Application) Approval</td>
<td>2018 w/BTD</td>
</tr>
<tr>
<td>Published studies – 2 in HIV; 2 in Inflammatory Diseases</td>
<td>2017</td>
</tr>
<tr>
<td>Conference Presentations at CROI and ASM Microbe</td>
<td>Completed &amp; Ongoing</td>
</tr>
<tr>
<td>Monotherapy Phase 2b/3 Investigative Trial Readout</td>
<td>2018</td>
</tr>
</tbody>
</table>