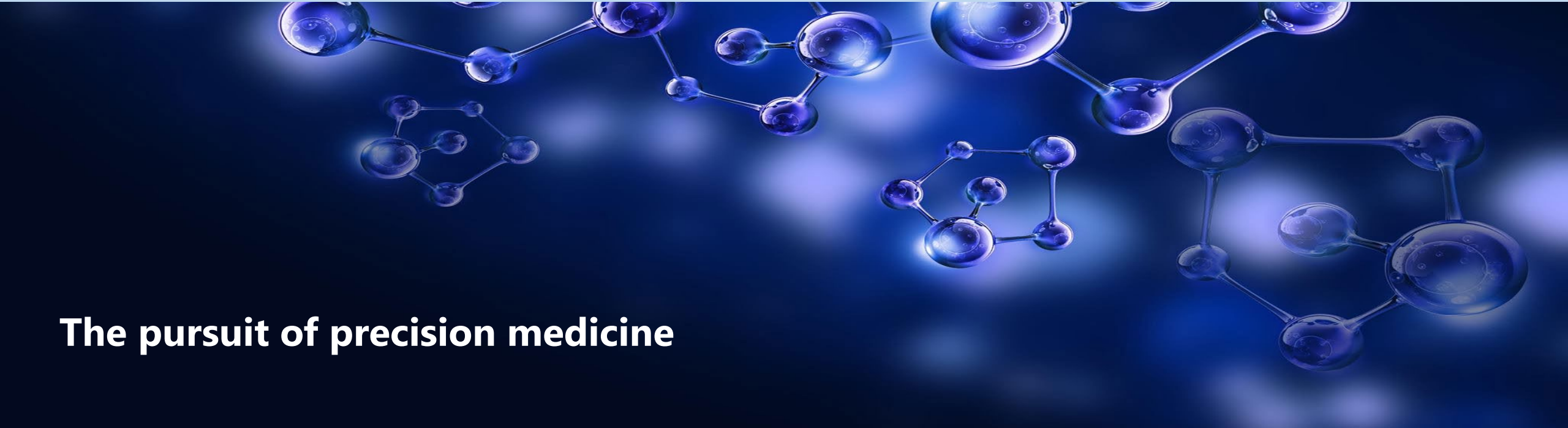
CytoDyn

September 30, 2020

ANNUAL MEETING OF STOCKHOLDERS

CYDY : OTCQB



The pursuit of precision medicine

Accomplishments over the past 12 months of the CytoDyn Team

Clinical trials (2020)

1) Completed a Phase 3 investigational trial in HIV (monotherapy).
2) Initiated & enrolled 10 patients in a Phase 2 basket trial in cancer for 22 solid tumor cancers.
3) Initiated and completed a Phase 2 in COVID-19.
4) Initiated a Phase 3 in COVID-19 severe/critical population with interim analysis a few days away.
5) According to doctors and patients involved, we saved lives of many COVID-19 severe/critical population by making leronlimab available under eIND for over 60 patients. Many patients credited our press releases for learning about leronlimab's potential in COVID-19.
6) BLA planned for re-submission to FDA in 2020 and also submission to other countries.

Licensing agreements

Completed two licensing agreements for the future launch and commercialization in U.S. upon approval.

HIV: Includes $4.5 million equity purchase future milestone payments of $87 million and 50% sharing of revenues.

COVID-19: Immediate distribution network available with American Regent, a Daiichi Sankyo Group Company.

Share price, liquidity and market cap (2020)

Trading volume in terms of dollars totaled approximately $90 million in 2019.

Through first 10 months of 2020, trading volume totaled over $4 billion.

Market cap peaked at approximately $6 billion, currently at approximately $2 billion, a 20x increase over a year ago.

Fund-raising

Effectiveness of capital raising resulted in material reduction in dilution

2018 and 2019- Raised ~ $112 million – Share diluted ~ 397 million
2020 (10 months)-Raised ~ $100 million – Shares diluted ~ 28 million

PR/IR activities (2020)

Total number of shareholders one year ago approx.	3,500
Total number of shareholders now is approximately	43,000
On Oct-18-2019 the CYDY stock hit a low of	$ 0.26
On June-30-2020 the CYDY stock hit a high of	$10.01

Clinical Update COVID-19 – Phase 2, CD10 (mild-to-moderate) – **Population Description**

86 patients were randomized but only 84 received treatment
Two populations for all the analysis (mITT[1] and PP[2])
mITT = 84 patients – 56 leronlimab vs 28 placebo
PP = 69 patients – 46 leronlimab vs 23 placebo

Mild-to-Moderate CD-10 Trial	n	Control	Leronlimab
Modified Intent to Treat population	84	28	56
Baseline Total Symptom Score ≥4	45	15	30
Baseline Total Symptom Score <4 to ≥1	31	10	21
Baseline Total Symptom Score = 0	8	3	5

[1] mITT – Modified Intent To Treat
[2] PP – Per Protocol

Clinical Update COVID-19 – Phase 2, CD10 (mild-to-moderate) – **Safety**

Leronlimab	Placebo
5 patients had 8 SAEs	6 patients had 11 SAEs
5 patients out of 56 ~ 9%	6 patients out of 28 ~ 21%
8 SAE among 56 ~ 14%	11 SAEs among 28 ~ 39%
96 AEs events in both arm ~ 33.9%	96 AEs events in both arm ~ 50%

[1] mITT – Modified Intent To Treat
[2] PP – Per Protocol

Clinical Update COVID-19 – Phase 2, CD10 (mild-to-moderate) – **Primary Endpoint**

Leronlimab	Placebo
At Day 3 - mITT Patients had improvement ~ 63%	At Day 3 - mITT Patients had improvement ~ 56%
At Day 3 – PP Patients with Total Symptom score ≥ 4 Improved ~ 90%	At Day 3 – PP Patients with Total Symptom score ≥ 4 Improved ~ 71%
At Day 14 – PP Patients with Total Symptom score ≥ 4 Improved ~ 96.3%	At Day 14 – PP Patients with Total Symptom score ≥ 4 Improved ~ 92.9%

[1] mITT – Modified Intent To Treat
[2] PP – Per Protocol

Clinical Update COVID-19 – Phase 2, CD10 (mild-to-moderate) – **Secondary Endpoint (NEWS2)**

NEWS2 **National Early Warning Score 2** **Based on: Respiration rate, oxygen saturation, any supplemental oxygen, temperature, systolic blood pressure, heart rate, level of consciousness**				
mITT[1] – Day 3	Leronlimab ~ 38%	vs	Placebo ~ 16%	$p = 0.0675$
mITT – Day 14	Leronlimab ~ 50%	vs	Placebo ~ 21%	$p = 0.0223$
PP[2] – Day 3	Leronlimab ~ 42%	vs	Placebo ~ 14%	$p = 0.0282$
PP – Day 14	Leronlimab ~ 55%	vs	Placebo ~ 23%	$p = 0.0185$

[1] mITT – Modified Intent To Treat
[2] PP – Per Protocol

Clinical Update COVID-19 – Phase 2, CD10 (mild-to-moderate) – **Other Secondary Endpoint**

Leronlimab	Placebo
Incidences of hospitalization ~ 1.79%	Incidences of hospitalization ~ 10.71%
Need for mechanical ventilation 1/56 ~ 1.79%	Need for mechanical ventilation 1/28 ~ 3.57%
Did not need oxygen use ~ 83.93%	Did not need oxygen use ~ 78.57%

[1] mITT – Modified Intend To Treat
[2] PP – Per Protocol

Clinical Update COVID-19 – CD10 Results Used to Design a Phase 3 and a New Phase 2

Next step after CD10 positive results
Pursuing Phase 3 for moderate population in COVID-19
Pursuing Phase 2 for Long Hauler population in COVID-19
Pursuing EAMS (Early Access Medicine Scheme) in UK by applying first for PIM (Promising Innovating Medicine)
Pursing EUA in Philippines

Clinical Update COVID-19 – Phase 2b/3, CD12 (severe-to-critical) – **Update**

Regulatory agency	**Update**
FDA	~220/390 Patients enrolled/total patients for trial Safety look after 100 **was positive** Interim after 195 (total death ~ 45) Interim analysis in October 2020
MHRA	Five sites are ready to initiate trial

Clinical Update HIV – Combination (BLA submission) and Monotherapy (Phase 3)

HIV			
Country	Regulatory agency	Meeting request	Timeline
US	FDA	BLA submission	2020
UK	MHRA[1]	Pre-BLA meeting	**Oct 22** is CytoDyn's pre-BLA meeting requested from MHRA
EU	EMA[2]	Pre-BLA meeting	Preparing to file
Canada	HEALTH CANADA	NDS (New Drug Submission)	Pre-application has been filed

[1] Medicine and Health product Regulatory Agency
[2] European Medicine Agency

Clinical Update CANCER – Phase 1b/2 and Phase 2 Basket Trial

Basket Trial
11 enrolled - 70 Screened
9 Pending eligibility
1 site (5 sites in selection process)

Compassionate Use – mTNBC
14 enrolled - 66 screened
16 pending eligibility
2 sites (4 sites in selection process)

Phase 1b/2 – mTNBC
3 enrolled – 3 screened
6 sites (8 sites in selection process)

eIND – Any stage 4 cancer
1 patient

Breakthrough Therapy Designation
CT scan
MRI
(CTC-CAML)-Currently analysis is being performed

Breakthrough Therapy Designation

mTNBC (6 months with Carboplatin + Leronlimab) – we need 5 patients
We have one

Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **NASH**

Potential role of leronlimab in NASH

"CCR5 plays a central role in all the events related to liver matrix remodeling and it has been observed that patients with chronic liver disease present high levels of CCR5 and CCL5."

"Our result suggests that in early NASH, HSCs secrete Ccl5 which contributes to a broad array of mechanisms by which hepatic steatosis and inflammation are achieved."

"Our data indicate that chemokine (C-C motif) ligand 5 (Ccl5, a.k.a. Rantes) is one of the HSC-secreted mediators in NASH that directly induce steatosis and pro-inflammatory factors in initially healthy hepatocytes."

From Dr. Ken Sherman: "It is possible that someday all patients with HIV may be treated with a blocking agent as part of their HIV drug cocktail designed to protect the liver and regain and maintain liver health," Dr. Ken Sherman suggests.

https://www.nature.com/articles/s41598-018-25699-9

Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **CANCER**

Potential role of leronlimab in CANCER
CCR5 is highly expressed in glioblastoma and is associated with poor prognosis of patients. CCL5/CCR5 is suggested to be an excellent new target for glioblastoma therapy. The molecular mechanisms, by which chemoattractant and receptor respond within the complex tissue microenvironment to promote cancer stem cells and tumour heterogeneity, should be considered in forthcoming studies." https://pubmed.ncbi.nlm.nih.gov/31747383/
"These results indicate that the expression of RANTES is directly correlated with a more advanced stage of disease, suggesting that RANTES may be involved in breast cancer progression. Moreover, it is possible that in patients diagnosed with benign breast disorders, RANTES expression may be indicative of an ongoing, but as yet undetectable, malignant process." https://cancerres.aacrjournals.org/content/59/18/4681.short
"Pathologic expression of CCR5 upon cellular transformation occurs in many types of cancer (**Fig. 1C**). CCR5 expression induced by transformation imbues the cell with dramatic alteration in gene expression, motility, and homing behavior to metastatic sites." https://cancerres.aacrjournals.org/content/79/19/4801
"CCL5 exerts proangiogenic effects by promoting endothelial cell migration, spreading, neovessel formation, and vascular endothelial growth factor (VEGF) secretion. Moreover, tumor cells, upon CCL5 stimulation, can produce VEGF or, by secreting CCL5, may recruit CCR5-expressing TAMs [**19**,**34**]. In turn, by secreting VEGF, TAMs can induce angiogenesis [**18**,**30**,**35**]. Thus, targeting tumor-promoting TAMs, which are now considered to be the major players in the regulation of tumor angiogenesis, may represent an attractive new therapeutic strategy." https://www.mdpi.com/1422-0067/19/5/1477/htm

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Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **MULTIPLE SCLEROSIS (MS)**

Potential role of leronlimab in MULTIPLE SCLEROSIS (MS)
"Thus, chemokines appear to be associated with MS and an increased chemokine expression may further enhance disease progression by attracting more leukocytes into the brain parenchyma and by activation of effector functions of astrocytes and microglial cells." https://onlinelibrary.wiley.com/doi/full/10.1046/j.1365-2249.2000.01334.x
"Individuals homozygous for a polymorphism in the CCR5 gene (CCR5D32) do not express a functional receptor, and although they are not protected from MS, they do exhibit a later age of disease onset and a lower risk of clinical recurrent disease activity." https://www.rndsystems.com/resources/articles/chemokine-receptors-and-multiple-sclerosis-pathogenesis
"Both MIP-1β as well as RANTES were found to be significantly elevated in brain tissue of MS patients." https://onlinelibrary.wiley.com/doi/full/10.1046/j.1365-2249.2000.01334.x
"CCR5 expression was increased during relapse, compared with control individuals. During remission, CCR5 values decreased, suggesting an association of $CCR5^+$ T cells with disease activity." https://jamanetwork.com/journals/jamaneurology/fullarticle/780942
"The cerebrospinal fluid (CSF) of patients with relapsing-remitting MS has $CCR2^+CCR5^+$ T_H1 cells during a relapse; $CCR5^+CD8^+$ T cells and $CCR5^+$ monocytes are higher in the CSF than in the blood of patients with the disease, and CCR5 is expressed in inflammatory cells infiltrating the CNS *in vivo* (17, 18). CCR5 is also expressed on immune cells within inflammatory lesions in MS and may contribute to recruitment of these cells to the inflamed tissue or to their activation. Finally, the expression of CCR5 ligands has been shown at sites of inflammation in MS (19). Interestingly, MS can develop in people who are homozygous for the CCR5Δ32 mutation. The CCR5Δ32 allele is not associated with MS risk (20, 21), but the disease seems to be less severe in carriers of the allele (22), suggesting that CCR5 antagonists might diminish disease activity." https://www.frontiersin.org/articles/10.3389/fimmu.2017.01981/full

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Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **AUTOIMMUNE DISEASES**

Potential role of leronlimab in AUTOIMMUNE DISEASES
"CCR5 may also have a role in autoimmune diseases. In rheumatoid arthritis, increased levels of CCR5 ligands CCL3, CCL4, and CCL5 are found in the synovial fluid (37, 38), and the CCR5Δ32 variant seems to protect from the disease (39). https://www.frontiersin.org/articles/10.3389/fimmu.2017.01981/full
"The predominance of CCR5-positive mononuclear cells in the synovial effusions of patients with arthritis suggests an important role for CCR5 in the process of joint inflammation, and identifies CCR5 as a possible new target for therapeutic intervention." https://onlinelibrary.wiley.com/doi/abs/10.1002/1529-0131(199905)42:5%3C981::AID-ANR17%3E3.0.CO;2-4
"CCL5 expression is increased in inflammatory bowel disease (IBD), likely pointing to a contribution by CCL5 in the progressive tissue destruction during the inflammatory processes (45). A recent investigation provided evidence that blocking CCR5 either by genetic ablation or by pharmacological inhibition with maraviroc rescued mice from colitis in both acute and chronic models (46)." https://www.frontiersin.org/articles/10.3389/fimmu.2017.01981/full
"In summary, CCR5 regulates recruitment of blood leukocytes into the colon indicating that targeting CCR5 may offer therapeutic options in IBDs." https://www.nature.com/articles/srep30802

Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **GvHD**

Potential role of leronlimab in GvHD
"Longer follow-up reveals a sustained reduction in acute GVHD incidence in maraviroc-treated patients compared with the control cohort, with a stronger effect on visceral vs skin GVHD and importantly no adverse impact on disease relapse, infections, or immune recovery. Thus, these data add further support that CCR5 blockade protects against GVHD." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5314813/
"Importantly, although CCR5 deficiency affects lymphocyte trafficking to target tissues, T cells would still be able to recognize pathogen-derived antigens.[5] Furthermore, humans with CCR5 deficiency are not grossly susceptible to infections, and in fact, we observed no increase in infection rate with maraviroc in our study. This suggests that maraviroc can dampen alloreactive T-cell responses while not impairing immunity against infections." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5314813/
"CCR5 is a marker for GVHD effector cells and that $CCR5^{+}$ T cells are active participants in the pathogenesis of human acute GVHD." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3182111/

Clinical Update CCR5 use in other indications – Potential indication for leronlimab – Stroke and Traumatic Brain Injury

Potential role of leronlimab in Stroke and Traumatic Brain Injury
"CCR5 is uniquely expressed in cortical neurons after stroke." "Post-stroke neuronal knockdown of CCR5 in premotor cortex leads to early recovery of motor control." "In a large clinical cohort of stroke patients, carriers for a naturally occurring loss-of function mutation in CCR5 (CCR5-D32) exhibited greater recovery of neurological impairments and cognitive function." "CCR5 is a translational target for neural repair in stroke and TBI and the first reported gene associated with enhanced recovery in human stroke." "Stroke and traumatic brain injury (TBI) are the leading causes of adult disability due to limited neurological recovery. Approximately 50%–60% of patients continue to experience motor impairments after stroke (Schaechter, 2004). 43% of those hospitalized for TBI suffer long-term disability (Ma et al., 2014)." "There have been no medical therapies developed to promote recovery in these conditions." https://www.sciencedirect.com/science/article/pii/S0301008204000565
CCR5 is differentially upregulated in neurons after stroke. • Knockdown of CCR5-induces motor recovery after stroke and improves cognition after TBI • Treatment with an FDA-approved drug, maraviroc induces recovery after stroke and TBI • Human carriers for CCR5delta32 have better outcomes after stroke • There have been no medical therapies to promote recovery in TBI and stroke.

Current trial status with leronlimab

One patient – One very strong anecdotal data

Clinical Update CCR5 use in other indications – Potential indication for leronlimab – **SEPSIS & SEIZURES**

Potential role of leronlimab in SEPSIS

CCR5-deficient mice are largely resistant to lethal *S. aureus* infection, highlighting the importance of CCR5 targeting in *S. aureus* pathogenesis. Thus, depletion of $CCR5^+$ leukocytes by LukED suggests a new immune evasion mechanism of *S. aureus* that can be therapeutically targeted.
https://www.nature.com/articles/nature11724

Potential role of leronlimab in SEIZURES

"Decrease in CCR5 in circulating cells strongly protected from excitotoxin-induced seizures, BBB leakage, CNS injury, and inflammation, and facilitated neurogenic repair."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3023386/

Leronlimab Past and Future Publications/Conference Presentations

Past Publications and Abstracts

HIV

- Monotherapy – CD01
- Phase 1: Jacobson et al, J.Infect. Dis 198:1345, *2008*
- Phase 2a (single dose): Jacobson et al, AAC, 54:4137, *2010*
- Phase 2a (variable dose): J Infect Dis. May 15; 201(10): 1481–1487, 2010

GvHD

- https://www.bbmt.org/article/S1083-8791(17)30810-8/fulltext

ASM

- 2016 – CD01, HIV, Monotherapy
- 2017 – CD02, HIV, Phase 3, Interim results
- 2018 – CD02, HIV, Phase 3 efficacy results only
- 2019 – CD02, HIV, Phase 3 efficacy and safety 24-week results

CROI

- 2017 – Monotherapy (2 years)
- 2019 – Monotherapy (350, 525, 700 mg)
- 2020 - Late breaker accepted then cancelled due to advance press release issuance

Future Publications and Abstract

HIV

- CD01, Phase 2 ext-Monotherapy (5 patients pass 6 years)
- CD02, Phase 3, with primary endpoint achieved
- CD03, Phase 3 ext-Monotherapy (over 200 reached ~ a year and over 40 pass 2 years with many pass 3 years)
- PrEP – Animal study
- Cure – Animal study

COVID-19 – Publications submitted

- eIND – 11 patients - Dr. Harish Seethamraju
- eIND – 30 patients - Dr. Otto Yang
- eIND – 4 patients- Dr. Nicholas Agresti
- CD10 – Phase 2, lead author is Dr. Seethamraju*

*not submitted yet

Abstract accepted for presentation

- Therapeutics for COVID-19

Revenue Potential Post Approval From Multiple Patient Categories

	2020	2021
Number of Patients Treated, ART (N)	**788,374**	**815,875**
Single-Tablet Regimens (STRs)	**514,020**	**564,586**
NNRTI-based STRs	**152,945**	**150,121**
Atripla (efavirenz/emtricitabine/TDF)	51,244	18,765
generic efavirenz/emtricitabine/TDF	-	23,660
Complera (rilpivirine/emtricitabine/TDF)	14,979	13,054
Odefsey (rilpivirine/emtricitabine/TAF)	71,742	76,692
doravirine/lamivudine/TDF	14,979	17,949
INI-based STRs	**251,491**	**268,423**
Stribild (elvitegravir/cobicistat/emtricitabine/TDF)	18,133	17,133
Genvoya (elvitegravir/cobicistat/emtricitabine/TAF)	78,837	81,588
Triumeq (dolutegravir/abacavir/lamivudine)	35,477	34,267
dolutegravir/lamivudine	59,128	64,454
bictegravir/emtricitabine/TAF	59,916	70,981
PI-based STRs	**36,265**	**38,346**
Prezista STR (darunavir/cobicistat/emtricitabine/TAF)	36,265	38,346
NRTI-free STRs (Short- and Long-Acting)	**73,319**	**107,696**
dolutegravir/rilpivirine	45,726	61,191
cabotegravir/rilpivirine	27,593	46,505
Multiple-Pill Regimen Components	**274,354**	**251,290**
Fixed-Dose NRTI Backbones and NRTIs	**275,143**	**267,607**
Truvada (emtricitabine/TDF)	81,991	30,187
generic emtricitabine/TDF	-	51,400
Descovy (emtricitabine/TAF)	96,970	98,721
Epzicom (abacavir/lamivudine)	3,153	1,632
generic abacavir/lamivudine	22,863	17,133
Viread (TDF)	6,307	4,079
generic TDF	25,228	24,476
Other Fixed-Dose NRTI Backbones	3,153	3,264
Other NRTIs	35,477	36,714
NNRTIs	**25,228**	**22,029**
Sustiva (efavirenz)	788	816
generic efavirenz	2,365	2,448
Intelence (etravirine)	1,577	816
Edurant (rilpivirine)	1,577	816
MK-1439 (doravirine)	18,133	16,318
generic nevirapine	788	816
PIs	**137,965**	**128,500**
Prezista (darunavir)	3,942	2,448
generic darunavir	42,572	44,057
Prezcobix (darunavir/cobicistat)	18,133	16,318
Reyataz (atazanavir)	7,095	2,448
generic atazanavir	15,767	13,870
Evotaz (atazanavir/cobicistat)	13,402	12,238
Kaletra (lopinavir/ritonavir)	1,577	816
generic lopinavir/ritonavir	10,249	10,198
generic fosamprenavir	1,577	1,632
Other PIs	23,651	24,476
INIs	**111,161**	**100,353**
Tivicay (dolutegravir)	67,012	62,822
Isentress (raltegravir)	44,149	37,530
Number of Patients Treated, Add-on & Salvage Therapies (N)	**85,933**	**49,768**
Attachment, Entry, and Fusion Inhibitors	**18,921**	**17,949**
Fuzeon (enfurvitide) – Selzentry – Fostemsavir-Ibalizumab	-	-
Pharmacokinetic Enhancers (Boosters)	**67,012**	**31,819**

Add PRO 140 to any STR

SCENARIO A

Most Likely:

1) ~100% suppression rate
2) Very few switches
3) Adherence increases dramatically
4) Resistance almost zero
5) Side effect + toxicity added by PRO 140 is almost zero

Add PRO 140 to any 2 pill-combination or to any 1 pill

SCENARIO B

New HAART with 2 pill combination acting as STR like the above

Example: **Truvada + PRO 140**

or

2 combination that acts as HAART.

Example: **Dolutegravir + PRO 140**

POSSIBLY: ~100% SUPPRESSION RATE

SCENARIO C

PRO 140 use as “add-on” to any combination

Trading History – Fund Raising - Dilution

Year	Total traded	$-Traded	Total ($) Raised	Total Dilution
2008	1,319,100	570,593	1,268,000	
2009	1,443,800	1,303,837	2,222,200	
2010	2,494,400	3,997,954	2,181,000	
2011	5,734,100	14,358,161	4,431,861	
2012	9,448,600	13,992,695	6,156,750	33,658,389
2013	6,446,800	6,101,525	15,858,500	25,457,786
2014	15,181,700	13,258,855	2,777,333	3,025,985
2015	20,628,700	18,005,475	24,693,613	50,852,916
2016	68,135,900	65,431,355	33,397,503	59,521,163
2017	48,672,800	32,031,997	22,504,057	67,054,821
2018	70,710,900	40,384,985	48,939,013	203,894,671
2019	185,081,500	92,052,061	58,214,271	193,060,864
2020-Sep-25	1,161,788,000	4,070,752,199	99,724,991	28,372,809

Corporate Priorities: 2020 - 2021

Clinical:

- Conclude CD12 Phase 3 trial for COVID-19 (severe/critical)
- Initiate Phase 2 trial for COVID-19 Long Haulers
- Initiate Phase 3 trial for COVID-19 Moderate
- Initiate Phase 3 trial for NASH

Regulatory:

- Complete HIV BLA filing
- Advance COVID-19 CD10 and CD12 results towards approval

New Indications:

- Accelerate the evaluation of multiple sclerosis, stroke, traumatic brain injury, sepsis, seizures, and various autoimmune diseases