



OTCQB: CYTR

Corporate Overview April 2021

Non-Confidential

CytRx Safe Harbor Statement

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CytRx Highlights

- CytRx's milestone and royalty agreement with Orphazyme for arimoclomol represents potential near term payments to CytRx
- Orphazyme has filed a New Drug Application (NDA) with the FDA for arimoclomol for NPC, which is currently under Priority Review with a target action date of June 17, 2021
- It also submitted a Marketing Authorisation Application with EMEA authorities for arimoclomol for NPC
- Orphazyme expects read-outs for its registrational trial in ALS in H1 2021.
- ImmunityBio has initiated a Phase 2 registrational-intent study for first-line and second-line locally advanced or metastatic pancreatic cancer, which includes aldoxorubicin
- Centurion BioPharma is a private oncology drug development company focused on cancer and has completed extensive pre-clinical work for its ultra high potency LADR™ drug candidates and albumin companion diagnostic (ACDx)



CytRx has potential milestone/royalty payments and a subsidiary called Centurion BioPharma

Orphazyme
Milestones
and Royalties

Orphazyme: \$120M in potential milestones; plus royalties on arimoclomol

ImmunityBio Milestones and Royalties

ImmunityBio: \$343M in potential milestones; plus royalties on aldoxorubicin

Centurion BioPharma Pipeline

Oncology drug development with a companion diagnostic

Centurion BioPharma is a subsidiary of CytRx



CytRx milestones and royalties from Orphazyme for Arimoclomol

Orphazyme Milestones and Royalties

Orphazyme: up to \$120M in milestones in addition to royalties on arimoclomol

Niemann-Pick disease ("NPC")

- Orphazyme filed an NDA with the FDA with Priority Review, and a target action date of June 17, 2021; also submitted an MAA with the EMA, both for arimoclomol for Niemann-Pick disease Type C (NPC).
- Orphazyme has also received Breakthrough Therapy Designation for NPC.
- Orphazyme launched an Early Access Program for NPC in January 2020 to further accelerate access to treatment with arimoclomol for people living with NPC.
- Total worldwide patients approximately 3,000.
- Expected price range is \$300,000 \$600,000; market potential \$600 Million.
- Go to market in US Q3 2021 and EU/RoW H2 2021.





WHAT IS NPC? Niemann-Pick Disease Type C

NPC IS A RARE, INHERITED, PROGRESSIVE, AND OFTEN FATAL NEURODEGENERATIVE DISEASE

NPC is a lysosomal storage disorder caused by genetic mutations that often lead to misfolded variants of NPC proteins. Misfolded NPC protein does not function properly and is subject to rapid degradation.



1-2000

people are diagnosed with NPC in the USA and EU





The disease affects the brain, liver, spleen and lungs. Often patients succumb to the disease before reaching the end of their teens.

The disease is progressive and patients gradually loses:

Motor function and coordination



95% have mutations in the NPC1 gene



is currently approved to treat NPC (Zavesca).



DIAGNOSIS

Difficult to diagnose, NPC is often diagnosed by ruling out other diseases, which may take years.





Source: www.orphazyme.com

Orphazyme – Amyotrophic Lateral Sclerosis (ALS)

Amyotrophic Lateral Sclerosis (ALS)

- Enrollment completed in P3 trial last July 2019.
- Fast Track Designation from the FDA received in May 2020.
- Announcement of P3 results in ALS in H1 2021.
- Regulatory submission in H2 2021.
- Expected price range of \$150,000 to \$450,000.
- Worldwide market potential of \$1.0 Billion to \$2.4 Billion.



Orphazyme - Inclusion Body Myositis

Inclusion Body Myositis (IBM)

- Phase 2 24 patient pilot trial results where arimoclomol treated patients were stabilized versus 25% on placebo. 4 months of continuous treatment resulted in a 60% reduction in progression, at 8 months, there was a 75% reduction, and at 12 months there was a 40% reduction.
- Phase 2/3 trial is fully enrolled. Study is completed and Orphazyme recently announced the study did not meet its primary or secondary endpoints.
- Orphazyme is continuing to analyze the data and will then announce a complete result of their findings in a future scientific forum.
- Estimated 40,000 patients in US/EU.



Source: www.orphazyme.com

Orphazyme preparing for commercialization in 2021 for arimoclomol

Orphazyme: Preparing for commercialization in 2021 PDUFA date June 2021 for NPC



Building a highly specialized commercial footprint in US and EU



Source: www.orphazyme.com

CytRx potential milestones and royalties from ImmunityBio for aldoxorubicin

ImmunityBio Milestones and Royalties

ImmunityBio: up to \$343M in milestones In addition to royalties on aldoxorubicin

- ImmunityBio has merged with NantKwest and trades under IBRX
- ImmunityBio has highlighted aldoxorubicin as one of three separate modalities of its platform
- ImmunityBio announced initiation of a phase 2 registrational-intent study using aldoxorubicin in combination with immunotherapy in metastatic pancreatic cancer
- ImmunityBio, to date, plans to use aldoxorubicin in studies in glioblastoma, triple negative breast cancer, in addition to metastatic pancreatic cancer.
- CytRx is entitled to increasing double-digit royalties on aldoxorubicin for soft tissue sarcomas and increasing single-digit royalties for all other indications
- ImmunityBio is reviewing options in Soft Tissue Sarcoma



CytRx partnered Pipeline with ImmunityBio - aldoxorubicin

Aldoxorubicin	Preclinical	Phase 1	Phase 2	Phase 3	
2 nd -Line Soft Tissue Sarcoma	Ph 3 – Completo	Ph 3 – Completed; NantCell has IND			
		•			
Combo with ifosfamide – STS	Ph 1b/2 – Nanto	Cell has IND			
Combination Trials with Immuno	therapy				
Pancreatic Cancer	Ph 2/3 – Enroll	ing			
Triple-Negative Breast Cancer	Ph 3 – Confirm	ng protocol design			
Recurring Glioblastoma	Ph 2 – Confi	ming protocol design			



CREATING TOMORROW, TODAY.

Update from NantKwest/ImmunityBio at JP Morgan Conference in January 2021

Metastatic Pancreatic Cancer QUILT-88: early indications of increased survival rate with no other approved treatment options

- In initial QUILT trials, median overall survival rate more than doubled compared to historical controls
- A single-arm Phase 2 trial was initiated in October 2020, for which the primary endpoint is overall survival and 83% of patients enrolled with second-line or greater pancreatic cancer remain alive to date
- Former Senate Majority Leader Harry Reid's stage IV pancreatic cancer is now in "complete remission" after receiving this experimental combination immunotherapy that included aldoxorubicin
- Initiation of a <u>Registrational-Intent</u> Phase 2 randomized, two-cohort, open-label study for first and second-line treatment of locally advanced or metastatic pancreatic cancer
- Randomized trials in first and second-line pancreatic cancer are actively recruiting at three sites with more than 50 patients enrolled or being evaluated in QUILT-88 to date



CytRx subsidiary Centurion BioPharma has an oncology preclinical pipeline and diagnostic

Centurion BioPharma Pipeline

Oncology drug development with a companion diagnostic

LADR™ (linker activated drug release) <u>albumin</u> binding drug conjugates

LADR-7 (auristatin)

LADR-8 (auristatin)

LADR-9 (maytansinoid)

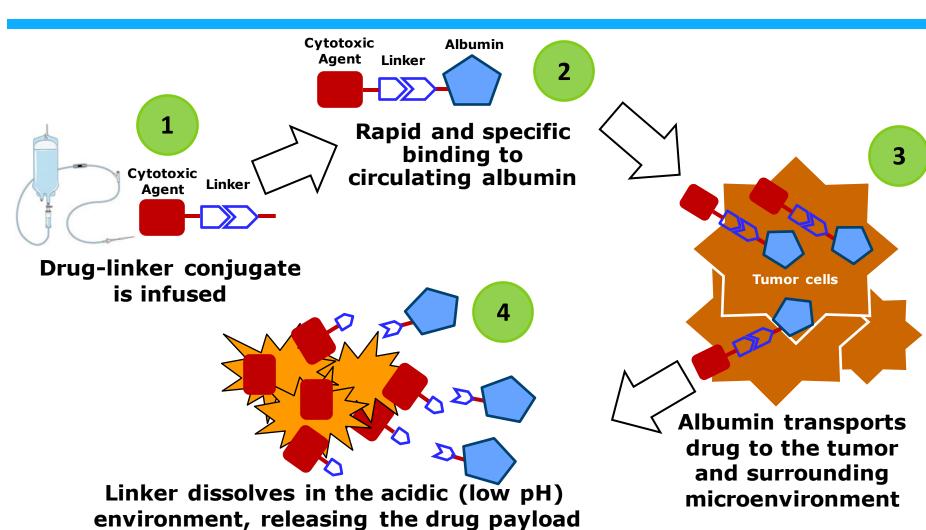
LADR-10 (maytansinoid)

Albumin companion diagnostic (ACDx)

identifies tumors eligible for treatment with LADR™



LADR™ Mechanism of Action





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Recent and Upcoming Catalysts

2020-2021

- √1H 2020: Orphazyme filed for FDA approval for arimoclomol in NiemannPick Type C disease with a target action date of 03/17/21
- √2H 2020: Orphazyme has submitted for EMEA (Europe) approval for arimoclomol in Niemann-Pick Type C disease
- 2021: Upon approval, CytRx is to receive a \$12 million milestone payment if the US, Europe and Japan are approved (\$6 million for US, \$4 million for Europe and \$2 million for Japan)
- 1H 2021: Orphazyme to announce top line results from the full analysis of registrational phase 3 clinical trial of arimoclomol in amyotrophic lateral sclerosis (ALS)



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Financial Summary

Cash Position (12/31/2020)

\$10.0M

No Debt

Shares Outstanding

36.5M

• **Options** Weighted-average strike price: \$7.43

3.2M

Fully-Diluted Share Count (12/31/2020)

39.7M



Summary

- Orphazyme could deliver milestones and royalties
- ImmunityBio could deliver milestones and royalties
- Cash burn rate is ~\$407k per month
- Potential to shelter future income with non-restrictive net-operating carry-forward losses ("NOL's") of \$258 million

