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### **OTCQB: CYTR**

## Corporate Overview March 2021

**Non-Confidential** 

# **CytRx Safe Harbor Statement**

THIS PRESENTATION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE CERTAIN RISKS AND UNCERTAINTIES. ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF VARIOUS RISKS AND UNCERTAINTIES, INCLUDING THOSE RISK FACTORS DISCUSSED IN THE ANNUAL AND QUARTERLY REPORTS THAT CYTRX FILES WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION.

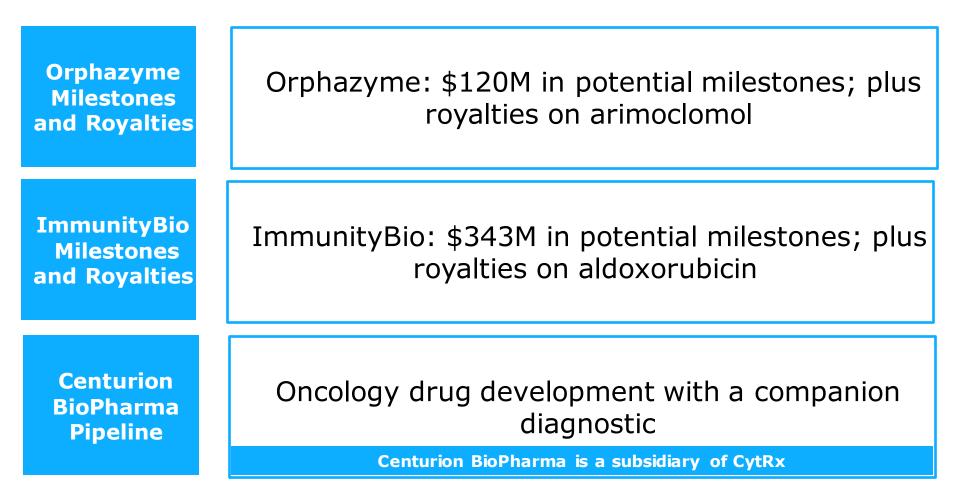


# **CytRx Highlights**

- 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 trials in ALS and IBM 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<sup>TM</sup> drug candidates and albumin companion diagnostic (ACDx)



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





## CytRx milestones and royalties from Orphazyme for Arimoclomol

Orphazyme Milestones and Royalties

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

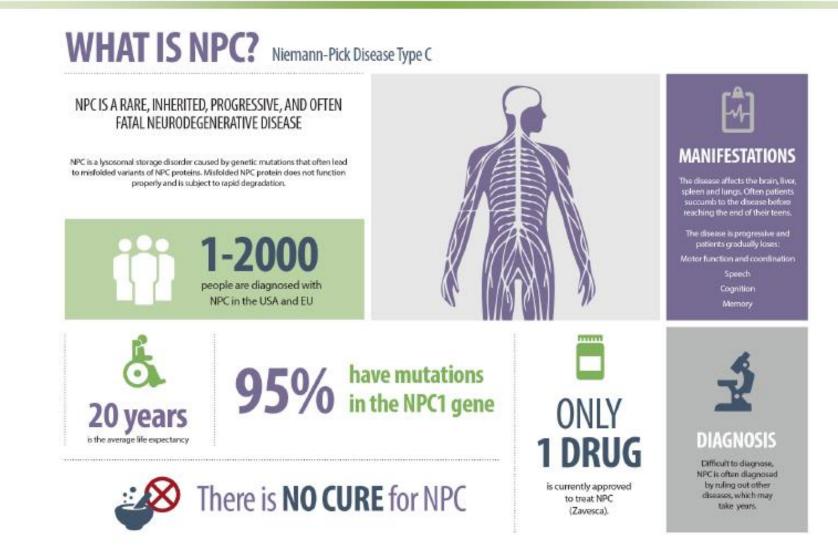
### Niemann-Pick disease ("NPC")

- 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.



### Niemann-Pick Disease Type C (NPC)





#### Source: www.orphazyme.com

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## **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 results are expected in H1 2021 and regulatory submission in H2 2021.
- Estimated 40,000 patients in US/EU.
- Expected price range per patient is \$150,000 \$450,000.
- Worldwide market potential is \$1.0 Billion to \$2.4 Billion.



## Orphazyme – Amyotrophic Lateral Sclerosis (ALS)

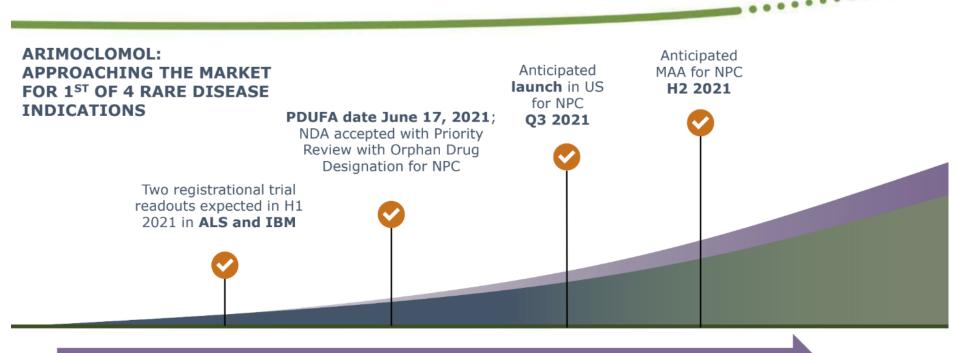
### Amyotrophic Lateral Sclerosis (ALS)

- 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 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



# CytRx potential milestones and royalties from ImmunityBio for aldoxorubicin

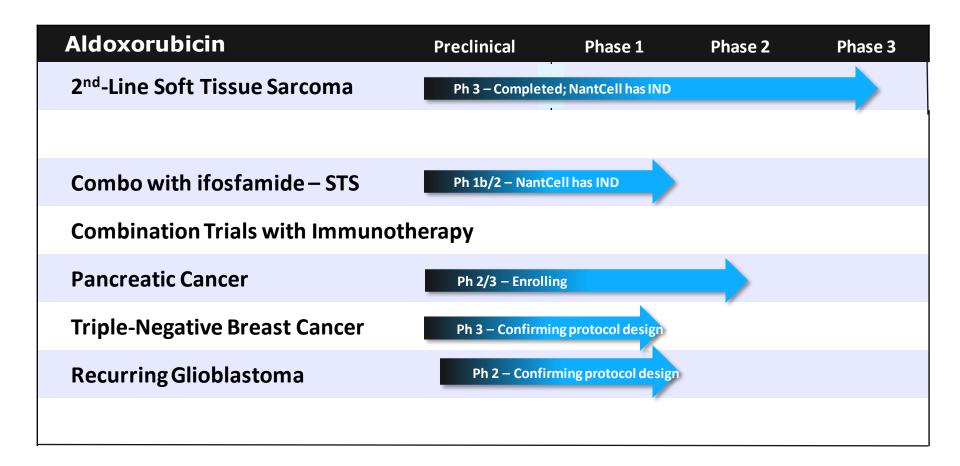
ImmunityBio Milestones and Royalties

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

- ImmunityBio recently announced it was merging with NantKwest (NK)
- 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





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

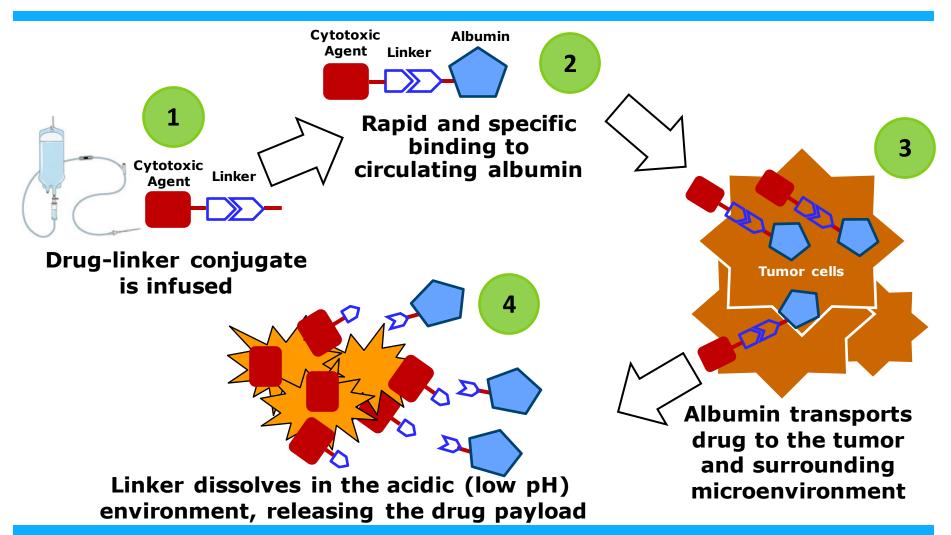
LADR-7 (auristatin) LADR-8 (auristatin) LADR-9 (maytansinoid) LADR-10 (maytansinoid)

### Albumin companion diagnostic (ACDx)

identifies tumors eligible for treatment with LADR<sup>™</sup>



## **LADR<sup>TM</sup>** Mechanism of Action





# **Recent and Upcoming Catalysts**

### 2020-2021

- ✓ 1H 2020: Orphazyme filed for FDA approval for arimoclomol in Niemann-Pick 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
- 2020-2021: 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)
- 1H 2021: Orphazyme to announce results of IBM registrational phase 2/3 clinical trial



# **Financial Summary**

<ul> <li>Cash Position (12/31/2020)</li> </ul>	\$10.0M
<ul> <li>No Debt</li> </ul>	
<ul> <li>Shares Outstanding</li> </ul>	36.5M
<ul> <li>Options Weighted-average strike price: \$7.43</li> </ul>	3.2M
<ul> <li>Fully-Diluted Share Count (12/31/2020)</li> </ul>	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 approximately \$250 million

