PROSTATE CANCER RESEARCH – MAKING A DIFFERENCE!

JULY 10, 2018

TYPES OF RESEARCH AT PCC

BENCH / TRANSLATIONAL RESEARCH

- " bench to bedside"

CLINICAL TRIAL - Scientific study involving humans

Interventional:

- Compares treatment options within a patient population
- Aim: To determine the efficacy and safety of two or more treatments

Non-Interventional:

- Observational Studies
- Aim: To gain further knowledge of how drugs are working and being used in everyday life

PCC Summary of Studies – July 5, 2018

Recruiting Studies

Enrolment status	Enrolled	Investigators /	Study	Key Inclusion Criteria
Open	PCC: 1848 Goal: 8800 (all sites)	Donnelly, et all	**APCaRI** – Evaluation of potential biomarkers to help the clinical management of prostate cancer	• Pre-diagnosis (referred for biopsy) / Post-diagnosis of prostate cancer
Open	9 Goal: 5	Donnelly / Gotto/ Leong)	**HERO:** A study to evaluate the safety and efficacy of relugolix in men with advanced prostate cancer	• Candidate for at least 1 year of continuous ADT for the management of hormone sensitive advanced prostate cancer with one of the following: ○ Evidence of biochemical (PSA) or clinical relapse following local primary intervention ○ Newly diagnosed androgen-sensitive metastatic disease; or ○ Advanced localized disease not suitable for local primary surgical intervention
Open *New May 1/18*	12 Goal: 10	Gotto / Donnelly	**GURC** – Genitourinary Research Consortium, a multicenter study to document the course of advanced prostate cancer in Canada in terms of disease progression, real-world treatment, and patient management.	• Metastatic prostate cancer: ○ New mCSPC, diagnosis in past 3 months / no more than 90 days of ADT ○ mCRPC / 1st treatment for mCRPC started in past 3 months or scheduled to begin

Ongoing studies (enrolment closed):

- **EMBARK: 22 enrolled (Goal 5):** Study of Enzalutamide plus Leuprolide, Enzalutamide Monotherapy, and placebo plus Leuprolide in men with high-risk nonmetastatic prostate cancer progressing after definitive therapy
- **ARAMIS: 5 enrolled (Goal 5):** Study of ODM-201 in men with high-risk non-metastatic castration-resistant prostate cancer (m0CRPC)
- **COSMIC: 39 Enrolled (Goal 10):** Observational study of the use of Zytiga in clinical care of metastatic castration-resistant prostate cancer (mCRPC)
- **TITAN: 11 Enrolled (Goal 5):** Apalutamide plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Subjects with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)
- **SPARTAN 6 enrolled (Goal: 5):** ARN-509 in men with non-metastatic castration-resistant prostate cancer (m0CRPC)
- **Enzamet: 11 enrolled (Goal 5):** Enzalutamide as 1st line therapy for men with hormone sensitive metastatic prostate cancer (mHSPC)

2017 KEY ACCOMPLISHMENTS

Recruitment and retention

Ground breaking results (Apalutamide)

Ongoing Program growth

- 1600 study patient visits conducted (2016 = 1200)
- Over 100 patients followed in 2017 for investigational treatments
- APCaRI: 500 additional patients in one year (Total = 1701)

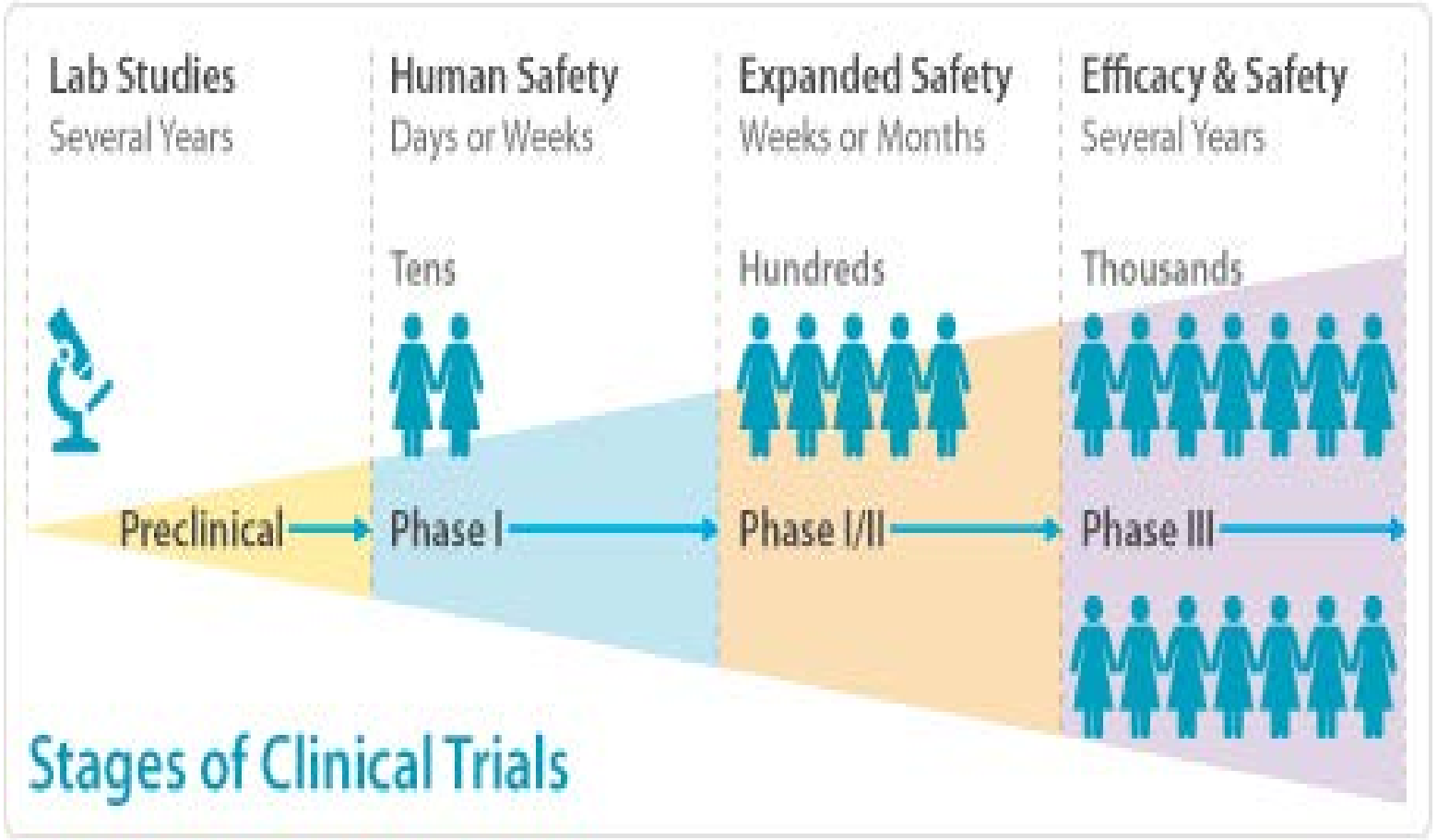
ALBERTA PROSTATE CANCER REGISTRY AND BIORESPOSITORY (APCARI)

<u>Purpose:</u> To identify new ways of detecting and predicting serious prostate cancer

<u>Population:</u> 8800 men with confirmed prostate cancer or men scheduled for a biopsy

<u>Methods:</u> biological samples and health information collected yearly for 5 years

PHASES OF CLINICAL TRIALS (ONCOLOGY EXAMPLE)



PHASES

- **Clinical trials for new treatments are done through *Phases*.**
- **Each phase is designed to answer specific research questions**
- **The next phase can only start after the previous phase has shown to be safe and effective.**
- **There are several phases involved in a clinical trial:**

PRE-CLINICAL

Wide doses of drug are tested:

- **In vitro (test tube or cell culture)**
- **In vivo (animal)**

PHASE 0

- **Uses a very small dose of a drug to study the effects in a small group of people**
- **Tests how the drug is used by and affects the human body.**
- **Not used to gather information about the safety of the drug or its effectiveness in treating cancer.**

PHASE I

- **How the new treatment should be given, how often, what is the safest dosage**
- **What effect the drug or therapy has on the body**
- **What side effects people taking the drug or treatment experience**
- **Small group of people (about 10-15)**

PHASE II

- **Learn more about how effective a treatment is for a certain type of cancer**
- **Continue to evaluate how safe the drug is and what effect is has on the body**
- **Small group of people (usually less than 100) with one type of cancer**

PHASE III

- **Find out whether the treatment being tested is better, as good, or worse than the standard treatment**
  - This includes evaluating quality of life and survival
- **Compare side effects of the new treatment and standard treatment**
- **Involves a large number of people (hundreds to thousands) at several different locations**

APPROVING A NEW DRUG OR TREATMENT

- **After clinical trials show that a new drug or treatment for cancer is safe and effective, it is submitted to Health Canada for approval.**
- **Once approved, it can be recommended for treatment to people with cancer**
- **It often takes more than 10 years for a new drug or treatment to go from preclinical trials, through clinical trials, to the approval process before it is available as a standard treatment to people with cancer.**

PHASE IV

- **Further evaluation of a drug after it has been approved for marketing**

- **Looks into risks and benefits in uncontrolled settings**

RULES, RULES, RULES!

Good Clinical Practice(GCP)

- An International ethical and scientific quality standard for conducting clinical trial
- Serves to protect the rights, integrity and confidentiality of trial subjects
- Provides a standard for countries to allow the mutual acceptance of clinical data
- Examples:
    - Clinical trials should be scientifically sound and described in a detailed protocol
    - Informed consent must be obtained from every subject prior to clinical trial participation

CONDUCTING THE STUDY

Pre Screen Phase

Patient recruitment

- Identifying the Patient Population
- Referrals

First patient contact

- Physician discussion / Consent to review medical records
- Overview of study / Eligibility criteria assessment

Ongoing contact

- Send Informed Consent Document
- Book Screen Visit & Imaging appointments

CONDUCTING THE STUDY

Patient Visits

Types of Visits:

- Screen
- Enrolment
- On Treatment
- Long Term Follow Up