



## RADIANT PHARMACEUTICALS CORPORATION

### National & Regional Cancer Screening Programs

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*This white paper provides a general outline of a new Radiant Pharmaceutical Corporation (“RPC”) National and Regional Cancer Screening Program (“NRCSP”) initiative to accelerate the government support process for Cancer Screening in countries that include Australia, Brazil, Canada, China, Columbia, France, Germany, India, Spain, Saudi Arabia, the United Kingdom and the United States.*

### What is a Cancer Screening Program?

Cancer Screening means screening “healthy” people who do not show any symptoms of disease for cancer, and people that have already been treated for cancer or may have cancer in their family history. The purpose of a Cancer Screening Program is to find cancers as early as possible, when the chances of curing the disease are the highest, to prevent cancer or detect it at a very early stage. Sometimes screening programs can find changes that without immediate treatment, could lead to cancer. [1] **Simply put, this means detecting cancer in stage one instead of stages three or four.**

### The Need for a Cancer Screening Program

Various countries have already established national screening programs for breast cancer, cervical cancer, bowel cancer, prostate cancer and ovarian cancer. [1] Yet, a far better screening strategy would be to initiate a *Cancer Screening Program* using a low cost multi-cancer detection test. **RPC’s Onko-Sure™ cancer test is the only cancer test shown to detect 15 different types of cancer and catch cancer in the stage one growth phase.** Onko-Sure™ is sold through RPC’s wholly-owned subsidiary, AMDL Diagnostics, Inc. (“ADI”). [2]

### National & Regional Healthcare Screening Initiatives

In countries that have national healthcare programs, RPC is requesting its new distribution partners to make an initial order of 1,000 Onko-Sure™ cancer test kits that can provide testing for approximately 42,000 patients in duplicate. These kits would then be delivered to various national testing laboratories and hospitals over a 90-day period in order to provide free cancer testing to individuals who have previously been diagnosed with cancer and individuals over the age of 50 years old where cancer testing is recommended as a part of their routine health examinations. This free cancer testing program should be done in conjunction with a robust public relations outreach program that in many cases may be supported by government health authorities. Select patient information and test results should be shared with the distribution partner and should be used to publish the results of the screening program. The goal is to seek immediate government funding of a new Nationwide Cancer Screening Program.

### Why Onko-Sure™ is a Key Cancer Screening Test

RPC’s Onko-Sure™ in vitro diagnostic cancer test enables physicians and their patients to effectively monitor and/or detect solid tumor cancers by measuring the accumulation of specific breakdown products in the blood called Fibrin and Fibrinogen Degradation Products (FDP). Onko-Sure™ is a simple, non-invasive blood test used for the detection and/or monitoring of 15 different types of cancer including: **lung, breast, stomach, liver, colon, rectal, ovarian, esophageal, cervical, trophoblastic, thyroid, malignant lymphoma, mouth, skin (melanoma), and pancreatic.** Onko-Sure™ can be a valuable diagnostic tool in the worldwide battle against cancer, the second

leading cause of death worldwide. Onko-Sure™ serves the IVD cancer/oncology market, which, according to Bio-Medicine.org, is growing at an 11% compounded annual growth rate. [2]

### **The Value Proposition of Onko-Sure™**

Onko-Sure™ is sold as a cancer screening blood test in Europe (CE Mark certified), India, Taiwan, Korea, Vietnam, and in Chile (for research use); is approved in the U.S. for the monitoring of colorectal cancer (CRC); approved in Canada (by Health Canada) for lung cancer detection and lung cancer treatment monitoring; and, in many key markets, has the significant potential to be used as a Cancer Screening test. [2]

### **Accelerated Path to Adopting Onko-Sure™ for Screening**

Because Onko-Sure™ is a non-invasive blood test there are no side effects to patients using the test. As with other cancer diagnostic products, false positive and false negative test results could pose a small risk to patient health if the physician conducting the test is not vigilant in following the Onko-Sure™ test results with other clinically-relevant diagnostic modalities. While the Onko-Sure™ test is helpful in diagnosing whether a patient has cancer, the attending physician should use other testing methods to determine and confirm the type and kind of cancer involved. [2]

### **Medical Usefulness of Onko-Sure™**

Clinical data supports the medical utility of Onko-Sure™ (AMDL-ELISA DR-70® (FDP) immunoassay) for the detection and monitoring of cancers in the ovaries, tongue, gastrointestinal tract, lung, breast, skin, mouth and colon/rectum. In the studies cited at the end of this document, Onko-Sure™ was used to measure FDP levels in 7,999 patients (see references on back). Within these studies, the Onko-Sure™ results consistently correlated with either the positive detection or positive progression of a variety of cancers. A complete list of references follows. [2]

### **How Onko-Sure™ Works**

While the production of Fibrin and Fibrinogen Degradation Products (FDP) is limited in healthy individuals, FDP are over produced by cancer cells, which release proteolytic enzymes such as plasmin and thrombin. Current assays for FDP usually measure a specific FDP component, such as D-dimer, as a representative of this group; whereas the Onko-Sure™ test detects the full complement of FDP. Onko-Sure™ acts as a “barometer for cancer” by simultaneously measuring the multiple FDP species that may be underestimated by other tests. [2]

### **Improving Cancer Survivability & Healthcare Outcomes**

For nearly all cancers, treatment options and survival are related to stage, which is generally characterized by the anatomical location and extent of disease. On this basis, it is assumed that the detection of cancer at an earlier stage will yield better healthcare outcomes.[6] At least two requirements must be met for cancer screening to be efficacious:

- A cancer test must be able to detect cancers earlier than if the cancer were detected as a result of the development of symptoms.
- Evidence must be available that treatment initiated earlier as a consequence of screening, results in an improved outcome.

### **Implementing a Cancer Screening Program**

Cancer screening is the presumptive identification of unrecognized disease or defects by means of tests, examinations, or other procedures that can be executed rapidly. In advocating screening programs as part of early detection of cancer, the success of screening depends on having sufficient numbers of personnel to perform the screening tests and on the availability of facilities that can undertake subsequent diagnosis, treatment, and follow-up.[3] A number of factors should be taken into consideration when the adoption of any screening technique is being considered:

- **Sensitivity:** the effectiveness of a test in detecting a cancer in those who have the disease;
- **Specificity:** the extent to which a test gives negative results in those that are free of the disease;
- **Positive Predictive Value:** the extent to which subjects have the disease in those that give a positive test result;
- **Negative Predictive Value:** the extent to which subjects are free of the disease in those that give a negative test result;
- **Acceptability:** the extent to which those for whom the test is designed agree to be tested.
- **High Mortality Rate:** The target disease should be a common form of cancer with high associated morbidity or mortality;
- **Effective Treatment:** An effective treatment, capable of reducing morbidity and mortality, should be available; and
- **Safe and Inexpensive:** A cancer test should be acceptable, safe, and relatively inexpensive.

### Typical Cancer Screening Guidelines

A national or regional cancer screening program should be organized to ensure that a large proportion of the target group is screened and that those individuals in whom abnormalities are observed receive appropriate diagnosis and therapy. [3] Guidelines to be applied in a national or regional cancer control program include:

- The frequency of screening and ages at which screening should be performed;
- Quality control systems for the screening tests;
- Defined mechanisms for referral and treatment of abnormalities; and
- An information system that can: send out invitations for initial screening; recall individuals for repeat screening; follow those with identified abnormalities and monitor and evaluate the program.

### Cancer Treatment Costs

The per patient cost for cancer treatment in 2010 is approximately US\$36,800. This amount does not take into account such related expenses as psychological counseling, doctor consultation fees, hospital stays and certain other factors. Cancer treatment costs may vary greatly depending on the severity of the cancer, the location and type, and the fame of the doctor. The following is a list of selected cancer statistics from seven various countries. [4]

- **Australia:** According to the Cancer Council, cancer is the second-biggest cause of death in Australia, following heart disease. It affects one in two Australians under the age of 85. The disease is expected to kill more than 43,000 people this year. Almost 12,000 more people die each year from cancer than 30 years ago, due mainly to population growth and ageing; however the death rate (number of deaths per 100,000 people) has fallen by nearly 15 percent. The incidence of cancer remains higher among men than women, largely due to the higher number of smoking-related cancers (higher smoking rates), melanoma (greater exposure to sun) and mesothelioma (greater exposure to asbestos). Prostate cancer is the most commonly diagnosed cancer in men, followed by colorectal cancer, lung cancer and melanoma. Breast cancer is the most common cancer among women, followed by colorectal, melanoma and lung cancer. Cancer treatment costs in Australia are AUD\$2.7 billion or US\$2.45 billion in direct health system costs (5.7%). [5][6]
- **USA:** According to the U.S. National Cancer Institute in 2009, an estimated 1,479,350 people in the United States will be diagnosed with cancer, and 562,340 will die of cancer. Estimates of the premature deaths that could have been avoided through screening vary from 3% to 35%, depending on a variety of assumptions. Beyond the potential for avoiding death, screening has been shown to reduce cancer morbidity since treatment for earlier-stage cancers is often less aggressive and less expensive than that for more advanced-stage cancers. The total cost of cancer in the USA in 2005 was US\$209.9 billion. US spending on cancer care has dramatically increased, yet its proportion of health expenditures has remained virtually constant. Use of the new drugs Avastin and Eloxatin have doubled survival rates for

metastatic colorectal cancer, while increasing treatment costs by 500-fold. [6]

- **Canada:** In 1998 the cost of treating cancer in Canada was US\$14.2 billion (9% of all disease costs, ranking third). [6]
- **Chile:** In Chile the treatment for smoking-related lung cancer accounted for 6% of total healthcare costs in 2004. [6]
- **France:** In France cancer hospitalizations within the public health system cost US\$6.2 billion in 1999 (23% for chemotherapy). Estimated total cancer drug sales in 2002 were US\$1.3–1.6 billion. [5]
- **Sweden:** In Sweden the total cancer drug sales rose from US\$37.3 million in 2000 to US\$118.7 million in 2004. [6]
- **The Netherlands:** In the Netherlands in 1999, the cost of cancer care was US\$1.2 billion. The cost of smoking-related healthcare for those aged 20 years and older was US\$514 million. [6]
- **United Kingdom:** In the U.K. the expenditure on cancer treatment by the National Health Service in 2001 was US\$3.2 billion (10.6% of all disease costs). [6]

### Colorectal Cancer Screening

Colorectal cancer screening is a significant public health issue in the United States. Approximately 50 percent of people of screening age are screened. Colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in both men and women in the U.S. In 2008 more than 148,000 people were diagnosed with colorectal cancer in the U.S. and nearly 50,000 people died of the disease. Colorectal cancer incidence and mortality rates are highest in African American men and women. These incidence rates among African Americans are more than 20 percent higher and mortality rates about 45 percent higher than those in whites. Among Hispanic men and women, colorectal cancer incidence and mortality rates are 20 percent to 30 percent lower than those among non-Hispanic whites. However, the rates among Hispanics in the U.S. are higher than in Spanish speaking countries in South and Central America. [7]

### Onko-Sure™ Cancer Screening Distribution Plan

RPC, through its wholly-owned subsidiary AMDL Diagnostics, Inc., seeks to develop new distribution relationships in various countries in order to develop a national or regional Cancer Screening Program using our Onko-Sure™ cancer test. RPC currently sells its Onko-Sure™ cancer testing kits, which can test up to 42 patients in duplicate, to distributors for US\$420.00 per kit or US\$10.00 per patient when patients are tested in duplicate. Typically, distributors then sell the Onko-Sure™ kits to laboratories, hospitals and clinics for US\$840.00 per kit or US\$20.00 per patient test in duplicate. In the case of a national health care screening program, the blood draw and testing process should add an additional cost of approximately US\$10.00 per patient tested. Thus, the cost to a government supported cancer screening test is approximately US\$30.00 per patient tested in duplicate.

### Cancer Screening Economics

**It has been estimated that a properly implemented cancer screening program can double the treatment savings, given the increasingly costly management of cancer. [8, 9, 10, 11, 12, 13, 14] In order to be conservative, in the analysis noted below a 25% savings on the annual costs for cancer treatment has been utilized. Screening is clearly desirable from the perspective of governments and insurance companies in the reduction of the incidence and mortality of cancer. We believe that, if approximately 30% of a population base that includes individuals over the age of 50 years of age and high-risk individuals are screened every two years, Onko-Sure™ will help to contain the increasing costs for the overall management of cancer treatments. This means that, if 15% of a country's or region's population is actually screened on an annual basis, the cost savings of a national or regional cancer screening program can be demonstrated. Please see the chart noted below.**

## Annual Savings of Cancer Treatment Costs From Screening

The chart noted below highlights the significant savings in healthcare costs when a *Cancer Screening Program* is implemented. The analysis includes the assumptions that 15% of a population would be screened on an annual basis, that the test would cost US\$30.00 per patient tested in duplicate, and that the typical program savings would generate a 25% reduction in cancer treatment costs due to detecting and treating cancer early.

Country	Population*	15% Annual Individuals Screened	Annual Screening Costs **	Annual Costs for Cancer Treatment	Potential Cancer Screening Savings***	Annual Savings after deducting Screening Cost
Australia	22.19 million	3.3 million	\$99 million	<u>\$2.45 billion</u>	<u>\$612 million</u>	<u>\$513 million</u>
Canada	30.04 million	4.5 million	\$135 million	<u>\$14.2 billion</u>	<u>\$3.55 billion</u>	<u>\$3.41 billion</u>
France	65.44 million	9.6 million	\$288 million	<u>\$6.2 billion</u>	<u>\$1.55 billion</u>	<u>\$1.26 billion</u>
U.K.	62.04 million	9.3 million	\$279 million	<u>\$3.2 billion</u>	<u>\$800 million</u>	<u>\$521 million</u>
U.S.A.	308 million	46.2 million	\$1.3 billion	<u>\$209 billion</u>	<u>\$52.2 billion</u>	<u>\$50.9 billion</u>

\*According to the United Nations Department of Economic and Social Affairs, July 1, 2009. \*\* All figures are in US dollars and are calculated at \$30.00 per patient tested in duplicate. \*\*\* Potential cancer Screening Savings is based upon a 25% reduction in cancer treatment costs, due to implementing a cancer screening program.

## Conclusions

RPC's Onko-Sure™ cancer test, if adopted as a cancer screen, represents a new driver in the quest to significantly reduce cancer related patient care costs and improve cancer patient outcomes & longevity. The information in this white paper illuminates the economic and improved healthcare benefits of our Onko-Sure™ cancer test for oncologists, general medical practitioners, cancer researchers, medical test distributors and government healthcare professionals. We welcome these professionals to contact RPC in order to discuss launching national and/or regional screening programs. Please contact [Radient Pharmaceutical Corporation](mailto:info@radient-pharma.com) at [info@radient-pharma.com](mailto:info@radient-pharma.com) or call 714-505-4460 to speak to either the Scientific Oversight Dept. or the International Sales Dept.

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