

**EXHIBIT “I”**  
**SETTLEMENT ELIGIBILITY CRITERIA**

**Unless otherwise indicated, all capitalized terms herein have the meanings set out in the Settlement Agreement.**

**1. PRODUCT IDENTIFICATION DOCUMENTATION and MANDATORY MEDICAL RECORDS**

1.1 In order to be eligible for compensation under the Settlement Agreement, each Claimant must provide evidence of the Class Member’s prescription(s) for PIO (*i.e.*, the products ACTOS® and/or APO-Pioglitazone and/or Sandoz-Pioglitazone), such evidence to consist of one or more of the following (“Product Identification Documentation”):

- a) all pharmacy records reflecting the dispensing of PIO to the Class Member, including the dosage and date(s) of same; **and/or**
- b) all insurance records reflecting the Class Member’s purchase of PIO, including the dosage and dates of same, if available; **and/or**
- c) medical records reflecting the prescription and/or provision (samples) of PIO to the Class Member, including the dosage and dates of same; **or**
- d) in extraordinary circumstances only, to be determined by the Claims Administrator, if none of the above records are available, a declaration signed by the Class Member’s physician attesting to the Class Member having been prescribed and/or provided with PIO, including the dosage and dates of same, along with a statutory declaration by the Class Member (or the Class Member’s representative) that the Class Member was prescribed and/or provided with PIO, along with the dosage and dates of same, and affirming that they have made reasonable best efforts to obtain the above records and providing the reason why such records could not be obtained.

1.2 In order to be eligible for compensation under the Settlement Agreement, each Claimant must also submit the following Mandatory Medical Records:

- a) pathology report(s) describing the existence of cancerous cells in the urothelial lining of the urinary bladder, renal pelvis or the ureter or confirming the diagnosis of bladder cancer on biopsy of excised tumor; **or**
- b) if no pathology report is available, other contemporaneous medical records referencing a pathology report containing a diagnosis of bladder cancer;  
**and**

- c) Complete Medical Records from all healthcare providers who diagnosed and/or provided the Class Members with treatment for their bladder cancer; **and**
- d) If not included in the above, Complete Medical Records from all healthcare providers who prescribed PIO to the Class Member from the date of such first prescription through to the Class Member's last use of PIO; **and**
- e) If not included in the above, Complete Medical Records from the Class Member's primary health care provider for the period spanning three (3) years prior to the Class Member's bladder cancer diagnosis through to the date of the Class Member's bladder cancer diagnosis; **and**
- f) If the death of the Class Member is alleged to be due to bladder cancer, a death certificate, autopsy report or other Medical Record reflecting that the primary or secondary cause of the Class Member's death was bladder cancer or complications due to the Class Member's bladder cancer.

## 2. DEFINITIONS AND EVIDENCE OF COMPENSABLE INJURIES

- 2.1 In order to be eligible for compensation under the Settlement Agreement, a Class Member must have suffered one of the following Compensable Injuries subsequent to the Class Member's first use of PIO:

**Level 1 – Single occurrence of bladder cancer, Ta or Tis, low grade, or a recurrence of bladder cancer originally diagnosed PRIOR to the Class Member's PIO usage** is established by medical records reflecting the following:

- a) The diagnosis of Ta or Tis, low grade (G1 or G2) bladder cancer, as determined by a pathology report;
- b) In the event that a pathology report does not exist or is not available, the Claims Administrator may conclude that the claim has been sufficiently proven by reference to contemporaneous medical records reflecting the applicable diagnosis; and
- c) Class Members with a diagnosis of bladder cancer that pre-dates usage of PIO, but who suffered one or multiple recurrences of bladder cancer diagnosed following usage of PIO.

**Level 2 – Ta or Tis high grade or T1 or recurrent bladder cancer**, is established by medical records reflecting the following:

- a) The diagnosis of Ta or Tis, high grade (G), **or**
- b) The diagnosis of T1 bladder cancer, **or**

- c) The diagnosis of a recurrence of bladder cancer, where “recurrence” is defined as a reappearance of cancer in the urothelial lining of the bladder, the renal pelvis or the ureter, documented in a pathology report where the original diagnosis of bladder cancer post-dated the Class Member’s first PIO usage.

**Level 3 – T2 or bladder cancer treated with radiation or chemotherapy** is established by medical records reflecting the following:

- a) The diagnosis of T2 bladder cancer, **or**
- b) Radiation therapy for the treatment of bladder cancer, **or**
- c) Systemic (oral or intravenous) chemotherapy for the treatment of bladder cancer (not including direct bladder instillation treatments).

**Level 4 – T3 or bladder cancer resulting in the complete or partial removal of a kidney and/or bladder** is established by medical records reflecting the following:

- a) The diagnosis of T3 bladder cancer, **or**
- b) Partial **or** complete cystectomy or nephrectomy for the treatment of bladder cancer, where cystectomy is defined as a surgical procedure to remove all or part of the urinary bladder and where nephrectomy is defined as a surgical procedure to remove all or part of a kidney.

**Level 5 – T4 or death due to bladder cancer** is established by medical records reflecting the following:

- a) The diagnosis of T4 bladder cancer, **or**
- b) Death from bladder cancer where an autopsy report or death certificate attributes the death to bladder cancer as a primary or secondary cause of death, or where contemporaneous medical records reflect that a qualified medical professional has determined that bladder cancer was the primary or secondary cause of death.

### **3. CUMULATIVE DOSAGE, RISK FACTOR AND OTHER ADJUSTMENTS**

3.1 All claims under the Settlement Agreement will be evaluated using a system with a base compensation value determined by both the severity of the Class Member’s bladder cancer diagnosis and the Class Member’s age at the time of that diagnosis, as set out in Exhibit “J” Settlement Compensation Grid.

That base compensation value will then be subject to adjustments relating to:

- a) The cumulative dosage of PIO ingested by the Class Member by the time of their bladder cancer diagnosis (“Cumulative Dosage Adjustment”); and
- b) Certain risk factors as set out below (“Risk Factors and Other Adjustments”).

3.2 The determination of the cumulative dosage will be based on the Product Identification Documentation submitted by or on behalf of the Class Member **AND** shall be based on dosage and not duration of use **UNLESS**:

- a) no documents exist which reflect the cumulative amount of PIO dispensed to the Class Member (to be established through documented proof that requests were made and that such records no longer exist); **and**
- b) contemporaneous medical records of the physician who prescribed PIO to the Class Member have been submitted by or on behalf of the Class Member and such record(s) reflect the prescription of PIO.

If a) and b) above are satisfied, the cumulative dosage may be considered on the basis of the duration of PIO usage reflected in the medical records of the physician(s) who prescribed PIO to the Class Member. If the medical records do not contain enough information to quantify the cumulative dosage of PIO, the Claims Administrator will make inquiries of the Class Member regarding his/her best recollection of the duration and dosage of PIO consumed. The Claims Administrator will consider this information, along with the medical records provided, to generate a reasonable estimate for cumulative dosage for the purposes of this claims process.

3.3 The following chart sets out the adjustments that will be applied to a Class Member’s base compensation value based on the Class Member’s cumulative dosage of PIO at the time of their bladder cancer diagnosis.

<b><u>Cumulative Dosage Adjustment</u></b>	
<b>Cumulative Dosage of PIO at Time of Bladder Cancer Diagnosis</b>	<b>Adjustment</b>
Less than 900 mg, and bladder cancer was diagnosed three years or longer <b>after</b> last use of PIO as documented in contemporaneous Pharmacy or Medical Records.	-90%
Less than 900 mg, and bladder cancer was diagnosed less than three years <b>after</b> last use of PIO as documented in contemporaneous Pharmacy or Medical Records.	-85%
≥ 900 mg and < 1,800 mg	-80%

≥ 1,800 mg and < 2,700 mg	-70%
≥ 2,700 mg and < 5,400 mg	-60%
≥ 5,400 mg and < 10,800 mg	-50%
≥ 10,800 mg and < 16,200 mg	-35%
≥ 16,200 mg and < 21,600 mg	-15%
≥ 21,600 mg and < 28,800 mg	no adjustment
≥ 28,800 mg and < 43,200 mg	+5%
≥ 43,200 mg and < 56,700 mg	+10%
56,700 mg and above	+20%

3.4 The following chart sets out the additional adjustments that will be applied to a Class Member's base compensation value based on a series of known risk factors for bladder cancer, which shall be disclosed by a Claimant in the Claim Form. The Claims Administrator shall determine which adjustments shall apply, based on a review of the Class Member's Mandatory Medical records.

<b><u>Risk Factor and Other Adjustments</u></b>	
<b>Adjustment Category</b>	<b>Adjustment</b>
<b>Diagnosis of bladder cancer prior to PIO use;</b> Claims assessed as Level 1 with no further risk factor or other adjustments applied.	-70%
<b>PIO usage continuing after April 19, 2012;</b> to be applied to Class Members whose PIO usage commenced <b>PRIOR</b> to April 19, 2012 and used PIO at any time thereafter. Only Class Members who commenced use of PIO prior to April 19, 2012 are eligible to receive compensation under the Settlement	-10%
<b>Smoking History</b> , as defined below; if there is uncertain or contradictory evidence in the Mandatory Medical Records regarding the proper categorization of a Class Member into one of the below categories (or the Class Member asserts a non-smoking status), the Claims Administrator shall assign such Class Member's Claim into the smoking category more favourable to the Class Member that may be reasonably supported based on the totality of the documentation submitted with the Claim Package <b>Current Smoker</b> , defined as a Class Member with a history of smoking within one year prior to bladder cancer diagnosis <b>Recent Smoker</b> , defined as a Class Member with a history of smoking between one and 5 years prior to bladder cancer diagnosis <b>Former Smoker</b> , defined as a Class Member with a history of smoking more than 5 years but less than 20 years prior to bladder cancer diagnosis	
	-50%
	-25%
	-10%

<b>Symptoms of bladder cancer (hematuria and/or pain with urination) prior to use of PIO</b> and within 2 years prior to bladder cancer diagnosis	-25%
<b>Diagnosis of bladder cancer more than 5 years after last use of PIO;</b> to be applied to Class Members where it is determined that the Class Member's bladder cancer was first diagnosed 5 years or more after the Class Member's last use of PIO as documented in the Product Identification Documentation and Mandatory Medical Records <b>and</b> the same records confirm that the Class Member's cumulative PIO dosage was <b>equal to or greater than 28,800mg.</b>	-33%
<b>Diagnosis of bladder cancer more than 5 years after last use of PIO;</b> to be applied to Class Members where it is determined that the Class Member's bladder cancer was first diagnosed 5 years or more after the Class Member's last use of PIO as documented in the Product Identification Documentation and Mandatory Medical Records <b>and</b> the same records confirm that the Class Member's cumulative PIO dosage was <b>less than 28,800mg.</b>	-66%
<b>Toxic Exposure;</b> to be applied to a Class Member's Claim if there is a reference in the Class Member's Mandatory Medical Records suggesting a causal association between the Class Member's bladder cancer diagnosis with a history of exposure to: coal gasification; diesel engine exhaust; iron or steel foundries; coke; coal tar; carbon black or shale oil extraction; wood impregnation; roofing; road paving; chimney sweeping; aluminum; carbon electrodes; production of rubber, leather, textiles, dyes or paint products; and/or past work as a painter, hairdresser, machinist, printer or truck driver	-50%
<b>Bladder cancer metastasized from other cancers;</b> to be applied to a Class Member's Claim where it is determined that the Class Member's bladder cancer originated in another organ and subsequently metastasized or spread to the bladder	-75%
<b>Cyclophosphamide use;</b> defined as the use of any pharmaceutical product containing the active pharmaceutical compound cyclophosphamide, including the branded medication known as "Cytoxan"	-25%
<b>Pelvic radiation;</b> defined as a history of radiation therapy to the pelvis prior to a diagnosis of bladder cancer, including for, but not limited to, the treatment of prostate, uterine, cervical, rectal or anal cancer	-25%