

# UroCryo™ Ablation

CLINICAL DATA REVIEW

2015



# Primary Prostate Data Summary

| Publication                           | Author                                | Average Follow-Up (months) | Number of Patients             | Timeframe (years) | BDFS                          | Failure Basis           | Rectal Injury     | Incontinence      | Potency         |
|---------------------------------------|---------------------------------------|----------------------------|--------------------------------|-------------------|-------------------------------|-------------------------|-------------------|-------------------|-----------------|
| 2014<br><i>J Urology</i> <sup>1</sup> | Levy, <i>et al</i><br>(COLD Registry) | > 60                       | 891<br>(with nadir <0.4 ng/mL) | 5                 | 90% (L)<br>81% (M)<br>74% (H) | ASTRO II<br>(Nadir + 2) | N/A               | N/A               | N/A             |
| 2012<br><i>J Urology</i> <sup>2</sup> | Levy, <i>et al</i><br>(COLD Registry) | > 60                       | 1,280                          | 5                 | N/A                           | N/A                     | 0.2%              | 3.4%              | 33%<br>(12 mo)  |
| 2010<br><i>Cancer</i> <sup>3</sup>    | Donnelly,<br><i>et al</i>             | 100                        | 122                            | 7                 | 73%                           | ASTRO II<br>(Nadir + 2) | 1%<br>(≥ Grade 3) | 1%<br>(≥ Grade 3) | 29%<br>(36 mo)  |
| 2008<br><i>Urology</i> <sup>4</sup>   | Cohen,<br><i>et al</i>                | 147                        | 370                            | 10                | 80% (L)<br>74% (M)<br>46% (H) | ASTRO II<br>(Nadir + 2) | N/A               | N/A               | N/A             |
| 2007<br><i>Urology</i> <sup>5</sup>   | Ellis, <i>et al</i>                   | 20                         | 416                            | 4                 | 84% (L)<br>82% (M)<br>69% (H) | ASTRO<br>(3 cons ↑)     | 0.0%              | 4.0%              | 51%<br>(48 mo)  |
| 2002<br><i>Urology</i> <sup>6</sup>   | Bahn,<br><i>et al</i>                 | 68                         | 590                            | 7                 | 92% (L)<br>89% (M)<br>89% (H) | ASTRO<br>(3 cons ↑)     | <0.1%             | 4.3%              | 5%<br>(Unaided) |

# Salvage Prostate Data Summary

| Publication                               | Author                                  | Average Follow-Up (months) | Number of Patients | Timeframe (years) | BDFS                          | Failure Basis           | Rectal Injury | Incontinence | Potency |
|---|---|----------------------------|--------------------|-------------------|-------------------------------|-------------------------|---------------|--------------|---------|
| 2012<br><i>J Urology</i> <sup>7</sup>     | Spiess, <i>et al</i><br>(COLD Registry) | 52                         | 132                | 5                 | 46%                           | ASTRO II<br>(Nadir + 2) | 0.7%          | N/A          | N/A     |
| 2008<br><i>J Urology</i> <sup>8</sup>     | Hamoui, <i>et al</i>                    | 95                         | 110                | 10                | 40% (BDFS)<br>80% (DSS)       | ASTRO II<br>(Nadir + 2) | N/A           | 41%          | N/A     |
| 2008<br><i>J Urology</i> <sup>9</sup>     | Ismail, <i>et al</i>                    | 33.5                       | 100                | 5                 | 73% (L)<br>45% (M)<br>11% (H) | ASTRO<br>(3 cons ↑)     | 1%            | 13%          | 14%     |
| 2005<br><i>Pros Can PD</i> <sup>10</sup>  | Donnelly,<br><i>et al</i>               | N/A                        | 46                 | 2                 | 58%                           | >1.0 ng/mL              | 2.2%          | 4.3%         | 85%     |
| 2003<br><i>Clin Pros Ca</i> <sup>11</sup> | Bahn, <i>et al</i>                      | N/A                        | 59                 | 7                 | 69%                           | >1.0 ng/mL              | N/A           | N/A          | N/A     |
| 2002<br><i>J Clin Oncol</i> <sup>12</sup> | Izawa, <i>et al</i>                     | 58                         | 131                | 5                 | 57% (L)<br>23%(H)             | ASTRO II<br>(Nadir + 2) | N/A           | N/A          | N/A     |

# Laparoscopic Renal Data Summary

| Publication                             | Author                    | Average Follow-Up (months) | Number of Patients | Local Control | Bleeding Requiring Transfusion |
|---|---------------------------|----------------------------|--------------------|---------------|--------------------------------|
| 2015 <i>Uro Onc</i> <sup>13</sup>       | Larcher, <i>et al</i>     | 48                         | 174                | 95%           | 8%                             |
| 2014 <i>Urology</i> <sup>14</sup>       | Kim, <i>et al</i>         | 71                         | 145                | 84%           | N/A                            |
| 2014 <i>Urology</i> <sup>15</sup>       | Johnson, <i>et al</i>     | 98                         | 92                 | 91%           | 5%                             |
| 2012 <i>Euro Uro</i> <sup>16</sup>      | Guillotreau, <i>et al</i> | 44                         | 220                | 89%           | 0%                             |
| 2011 <i>J Endourology</i> <sup>17</sup> | Klatte, <i>et al</i>      | 34                         | 41                 | 89%           | 0%                             |
| 2010 <i>Urology</i> <sup>18</sup>       | Tsivian, <i>et al</i>     | 20                         | 163                | 96%           | 1%                             |
| 2010 <i>J Urology</i> <sup>19</sup>     | Aron, <i>et al</i>        | 96                         | 80                 | 90%           | N/A                            |

# Key Terms

- ASTRO criteria for biochemical failure of prostate cancer treatment
  - 3 consecutive increases in PSA
- ASTRO II (Phoenix) criteria for biochemical failure of prostate cancer treatment
  - PSA Nadir + 2 ng/mL
- BDFS
  - Biochemical Disease-Free Survival
- DSS
  - Disease-Specific Survival
- L, M, H
  - Low Risk Patients, Moderate Risk Patients, High Risk Patients
- Local Control
  - No signs of tumor with contrast-enhanced CT or MRI
- Nadir
  - Lowest post-treatment PSA level

# References

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