Form 2127 R2.0: Renal Carcinoma Post-HSCT Data

Center: __________________________ CRID: __________________________

Key Fields

Sequence Number: __________________________
Date Received: __ __ __ __ - __ __- __ __
CIBMTR Center Number: __________________________
CIBMTR Recipient ID: __________________________

Today's Date: __ __ __ __
Date of HSCT for which this form is being completed: __ __ __ __

HSCT type: (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product type: (check all that apply)
- Marrow
- PBSC
- Cord blood
- Other product

Specify: __________________________

Visit:
- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years,

Specify: __________________________

Post HSCT Renal Carcinoma

Questions: 1 - 49

1 If this form is being completed for a 100-day visit, what was the recipient's disease status at 30 days post-HSCT? (Compared to last measurement of disease before transplantation.)
   (Disease status based on response criteria described below.)
   - complete response (CR)
   - Complete response with persistent imaging abnormalities of unknown significance (CRU)
   - partial response (PR)
   - Stable disease
   - Progressive disease
   - not evaluable, toxic death
   - Not evaluable
   - unknown / not tested / > 100-day follow-up

2 Date of disease status measurement at Day 30: __ __ __ __ - __ __

3 Specify reason disease status is unevaluable __________________________

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.
Retain the original form at the transplant center.

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What was the recipient's best response to HSCT? (Compared to last measurement of disease before transplantation; do not include results gained from post-HSCT therapy.)

- complete response (CR)
- Complete response with persistent imaging abnormalities of unknown significance (CRU)
- partial response (PR)
- Stable disease
- Progressive disease
- not evaluable, toxic death
- Not evaluable
- unknown / not tested

Date of disease status measurement at Day 30: __ __ __ __ - __ __ - __ __

Specify reason disease status is unevaluable: ________________________________

Did the recipient experience any disease progression post-HSCT?

- yes
- no
- Unknown

Date of progression/relapse unknown: __ __ __ __ - __ __ - __ __

Was there subsequent disease stability or regression without further therapy (so-called graft-versus-tumor effect)?

- yes
- no
- Unknown

Did this change in disease status qualify as a partial response or better if compared to a post-HSCT imaging study? (See page 1 for criteria to define partial response.)

- yes
- no

Was planned treatment given since the date of last report? (Include any maintenance therapy, but exclude any treatment for relapse/progressive disease.)

- yes
- no

Specify treatment(s) given post-HSCT:

Line of Therapy:

12 Was therapy planned?

- yes
- no

13 Date started therapy: __ __ __ __ - __ __ - __ __

14 Date stopped therapy: __ __ __ __ - __ __ - __ __

15 Systemic therapy:

- yes
- no

16 Number of cycles _______________ Unknown/not applicable

17 5-fluorouracil (5-FU):

- yes
- no

Questions: 12 - 48
<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Bevacizumab</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>19</td>
<td>Erlotinib</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>20</td>
<td>Floxuridine</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>21</td>
<td>Gemcitabine</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>22</td>
<td>High-dose interleukin-2 (IL2) (IV bolus or infusion):</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>23</td>
<td>Subcutaneous interleukin-2 (IL2):</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>24</td>
<td>Interferon-α</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>25</td>
<td>Provera</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>26</td>
<td>Sorafenib</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>27</td>
<td>Sunitinib (SU11248):</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>28</td>
<td>Thalidomide</td>
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</tr>
<tr>
<td>29</td>
<td>Other</td>
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<td>no</td>
</tr>
<tr>
<td>30</td>
<td>Specify other:</td>
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<td></td>
<td>Radiation Therapy:</td>
<td>yes</td>
<td>no</td>
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<td>32</td>
<td>Local / regional:</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>33</td>
<td>Specify total dose:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>Sites of non-contiguous metastases:</td>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>
cGy (rads)

35 Specify total dose: __________________________

36 Other site(s)
   [ ] yes [ ] no

37 Specify other site: __________________________

38 Specify total dose: __________________________ cGy (rads)

39 Surgery:
   [ ] yes [ ] no

40 Resection of primary tumor:
   [ ] yes [ ] no

41 Resection of metastases:
   [ ] yes [ ] no

42 Specify site(s) of metastases: __________________________

43 Best Response to Line of Therapy:
   [ ] complete response (CR) Disappearance of all target lesions for a period of at least one month
   [ ] complete response with persistent imaging abnormalities of unknown significance (CRU)
   [ ] partial response (PR) At least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters.
   [ ] Stable disease Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
   [ ] Progressive disease At least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
   [ ] not evaluable, toxic death
   [ ] Not evaluable
   [ ] unknown / not tested

44 Specify: __________________________

45 Date response evaluated: __ __ __ __ - __ __- __ __

46 Did patient relapse/progress following this line of therapy?
   [ ] yes [ ] no

47 Date of relapse/progress following this line of therapy? __ __ __ __

48 Specify site(s) of relapse: __________________________
 Were more than 2 instances of post-HSCT therapy given?

<table>
<thead>
<tr>
<th>yes</th>
<th>Copy and complete questions 12-48 until all instances of therapy have been reported.</th>
</tr>
</thead>
<tbody>
<tr>
<td>no</td>
<td></td>
</tr>
</tbody>
</table>

**Current Status of Renal Carcinoma**

**Questions: 50 - 52**

50 What was the recipient's disease status at this visit? (Compare 100-day measurement of disease to status before transplantation; all other time points compare to previous visit.)

- **complete response (CR)** Disappearance of all target lesions for a period of at least one month
- **Complete response with persistent imaging abnormalities of unknown significance (CRU)**
- **partial response (PR)** At least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
- **Stable disease** Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
- **progression or recurrence after remission** At least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
- **therapy-/immune-induced complete response after post-HSCT recurrence**
- **not evaluable, toxic death**
- **Not evaluable**
- **unknown/not tested**

51 Date of disease progression / recurrence: __ __ __ __ - __ __ __ __

52 Specify reason disease status is unevaluable: ____________________________

First Name: ____________________________ Last Name: ____________________________

Phone number: ____________________________ Fax number: ____________________________

E-mail address: ____________________________