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H. 知的財産権の出願・登録状況（予定を含む）

1. 特許取得、2. 実用新案登録

・赤塚美樹：

1)Cathepsin H タンパク質由来の CD8+ 細胞傷害性 T リンパ球 mHA エピトープペプチドおよびその用途（申請中）  
特願 2004-325328

・森尾友宏：

1)造血幹細胞移植後の生着安定組成物、該組成物を得るためのキット、造血幹細胞移植後の生着安定方法、ならびにヒトモノクローナル抗体あるいはヒトポリクローナル抗体の製法（特願 2004 - 138468、出願日 H16. 5. 7）。出願人：黒岩保幸(株)リンフォテック。発明者：関根暉彬、森尾友宏、清水則夫他。  
2)腫瘍・感染症および自己免疫疾患の予防・治療用 HLA 一致他人由来活性化リンパ球および該リンパ球を主成分

とする製剤ならびに該製剤の製造方法、該製剤調製用キット（特開 2004-2312）出願人：黒岩保幸(株)リンフォテック。発明者：関根暉彬、森尾友宏、清水則夫他。

3) 標的核酸の検出法（特願 2003-164799）出願人：清水則夫。発明者：関根暉彬、黒岩保幸、森尾友宏他。

4) 臍帯血由来活性化リンパ球及び該リンパ球を主成分とする製剤ならびに該製剤の製造方法、該製剤調製用キット（特開 2002 - 171966）出願人：黒岩保幸(株)リンフォテック。発明者：関根暉彬、森尾友宏、清水則夫他。

・池原 進：

1) A Method of Inducing Immunological Tolerance. 特開 2001-172188 特願 09-531891

2) 骨髄液採取セット及び骨髄針 特願 2001-241586 平成 13 年 8 月 9 日(未)  
権利者名：(株)日本抗体研究所

2) 悪性腫瘍の治療方法  
特願 2003-49198

平成 15 年 2 月 26 日(未)  
権利者名：関西 TLO (株)

3. その他

なし

### Ⅲ. 分担研究報告書

### Ⅲ. テーマー I

細胞治療とその適正運用

研究要旨：日本造血細胞移植学会との共同作業により、血縁造血幹細胞（骨髄・末梢血）ドナー事前登録・急性期有害事象報告・年次ドナー状況問い合わせ（同意が得られたドナーを対象に5年間）をセットにした血縁造血幹細胞ドナーフォローアップ事業を2005年4月より開始し、2006年3月からはこの事前登録と学会による適格性判定を加入条件としたドナー傷害保険を設定した。1年間のフォローアップの結果、わが国の血縁ドナーにおける骨髄：末梢血提供比率は約1：2であり、急性期有害事象報告は末梢血に多いものの重篤なものは発生していないことが示され、事前登録制が血縁ドナーにおける重篤有害事象を抑止する効果があることを推測させた。

#### A. 研究目的

同種造血幹細胞移植は健常ドナーが幹細胞提供後も完全な健康状態を維持できることを前提としている。健常ドナーの内、血縁末梢血幹細胞ドナーについては今までも日本造血細胞移植学会によって、非血縁骨髄ドナーについては骨髄移植推進財団によって、又、臍帯血ドナーについては日本さい帯血バンクネットワークによって、提供後のフォローアップが行われてきたが、唯一血縁骨髄ドナーだけはその歴史の古さ故にフォローアップシステムが無く、ドナーが真に提供後も健康状態を維持しているかどうか確かめる術が無かった。一部に血縁骨髄ドナーが提供後の後遺症に悩んでいるといった話を聞くにつけ、更には他の血縁臓（肝、腎等）提供者において比較的重篤な後遺症が発生しているとの報告を見るにつけ、血縁骨髄ドナーのための提供後の健康把握システムが無いことはもはや看過すべきではないと考え、日本造血細胞移植学会との共同作業として新たに血縁造血幹細胞（骨髄・末梢血）ドナーフォロー

アップ事業を開始した。

#### B. 研究方法

調査対象は2005年4月1日以降に造血幹細胞採取が行われたすべての血縁ドナーとし、重点調査項目は2005年4月1日以降に登録された血縁造血幹細胞採取後30日以内における重篤有害事象発生状況の把握と、上記の血縁ドナーのうち、調査協力の同意が得られたドナーを対象とした造血幹細胞提供後5年間の中長期的な安全性の確認を、郵送により調査するシステムを構築した（図-1）。システムの開始にあたり1）日本造血幹細胞移植学会ドナー委員会からの手紙、2）血縁造血幹細胞ドナーフォローアップ事業－実施要綱－、3）血縁造血幹細胞ドナー登録票を、同種造血幹細胞採取実施の可能性のある約2,000診療科に郵送した。

#### C. 研究結果

2005年4月から2006年4月末までの13ヶ月の事前登録数は705例で、骨髄提供：242例、末梢血提供：463例（骨髄：末梢血